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No. 04-

IN THE

Supreme Court of the United States

M. R. KNISLEY, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

PETITION FOR A WRIT OF CERTIORARI

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June 2005

QUESTION PRESENTED

Whether the preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §360k(a), preempts claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

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on behalf of the Estate of Margaret Brooks
George Copeland,
as parent and guardian of Scott Copeland
Linda Copeland,
as parent and guardian of Scott Copeland
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on behalf of himself and of the Estate of Mary Kulp
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RESPONDENT:
Medtronic, Inc.

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INTRODUCTION

In the years since the Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the federal and state appellate courts have become deeply divided on the question presented here: whether state-law damages claims concerning medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA") under the 1976 Medical Device Amendments ("MDA") are preempted. Today, an injured patient can maintain suit against the manufacturer of a PMA device in the courts of the Eleventh Circuit, for example, but not the Sixth Circuit, and in Illinois state courts, for example, but not in Illinois federal courts. In fact, three circuit courts have reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached two opposite conclusions. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption of state-law damages claims), *with* Pet. App. 1a (preemption), and *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). The persistent conflict among the lower courts cries out for this Court's review.

Since *Lohr*, this Court has denied review of petitions presenting substantially the same question presented here. *See, e.g., Martin v. Medtronic*, 534 U.S. 1078 (2002) (denying *cert.*); *Brooks v. Howmedica*, 535 U.S. 1056 (2002) (same); *Kemp v. Medtronic*, 534 U.S. 818 (2001) (same); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998) (same); *Surgidev Corp. v Niehoff*, 523 U.S. 1005 (1998) (same). For the most part, opponents of review suggested that the no-preemption decisions might somehow fade away or be overturned en banc. Now, however, nine years after the decision in *Lohr*, it is clear that the deep division among the lower courts will not be resolved without this Court's intervention.

Moreover, a significant number of appellate courts have erroneously reaffirmed broad pre-*Lohr* interpretations of the MDA's preemption provision, 21 U.S.C. § 360k(a). Like the Sixth Circuit, these courts have mistakenly held that the FDA's approval of a PMA application constitutes a specific preemption-triggering federal "requirement" under section 360k(a) and have failed to follow *Lohr*'s holding that claims based either on state-law duties of general applicability or state-law duties that parallel federal requirements are not preempted. *See Lohr*, 470 U.S. at 501-02. Several courts have done so by recasting Justice Breyer's concurring opinion in *Lohr* as the lead opinion and refusing to apply the majority's analysis, in which Justice Breyer himself joined. The Court should grant certiorari to correct this recurring misapplication of its precedent.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Sixth Circuit is reported at 405 F.3d 421, and is reproduced in the Appendix at 1a. The district court decision granting Respondent's motion for summary judgment in part is unreported and is reproduced in the Appendix at 8a. The district court decision denying Petitioners' motion for reconsideration is unreported and is reproduced at 25a. The district court decision granting Respondent summary judgment is unreported and is reproduced at 30a.

JURISDICTION

The judgment of the court of appeals was entered on April 21, 2005. Pet. App. 1a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 360k provides in part:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and

> Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. . . .

STATEMENT OF THE CASE

This case involves a suit to recover for injuries suffered by 14 individuals from pacemakers manufactured by respondent Medtronic, Inc. The court of appeals held that the MDA preempts Petitioners' claims.

Because an understanding of the structure of the MDA is important to understanding this case, Part A, below, offers a general description of the MDA. Part B describes the decision in *Medtronic v. Lohr*, in which the Court considered the scope of the MDA's preemption provision. Part C sets forth the facts of this case and the proceedings below.

A. The Medical Device Amendments.

The MDA's principal purpose was to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process by which devices could reach the market. H.R. Rep. 853, 94th Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq.*). Under the MDA, each medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853 at 34; 21 U.S.C. § 360c(a).

Class I devices, such as band aids, are the least risky and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See id.* § 360c(a)(1)(A).

Class II devices, such as hearing aids and tampons, are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). The FDA may therefore subject them to "special controls," such as the agency's specific warning language for tampon labeling. *See* 21 C.F.R. § 801.430(c), (d) & (e).

Class III devices—such as the pacemaker leads at issue here and in *Lohr*—are those that, in general, cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C.

§ 360c(a)(1)(C). This process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[1]

Three components of the regulatory structure are relevant to this petition. First, when the FDA approves a manufacturer's PMA application, it does not warrant that the device is free of defect in design, manufacture, or labeling. The FDA does not generate or specify the device's design, manufacturing process, or labeling, and it does not test or conduct studies of the device. Rather, a device's design, manufacture, and labeling originate with the device manufacturer, on whose data the FDA depends in acting on the PMA application. *See* 21 C.F.R. § 814.20, 814.44. When granting PMA, the FDA typically sends a form approval letter reminding the manufacturer of its obligations under federal regulations. There is nothing device-specific in the form approval letter.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, the FDA has issued design requirements for certain laser devices, *id.* § 886.4392, and absorbency testing

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[1] If the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. § 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for approving such devices is sometimes referred to as the "510(k)" process after the section of the Food, Drug, and Cosmetic Act under which the device application is submitted. *See Lohr*, 518 U.S. at 478.

requirements for tampons, *id.* § 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for pacemakers or their component parts, such as the pacemaker lead that caused Petitioners' injuries.

Third, the MDA contains a preemption provision, 21 U.S.C. § 360k(a), that preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to," MDA "requirements." Under 21 U.S.C. § 360k(b), the FDA may exempt from preemption state requirements that would otherwise be preempted. Implementing this authority, the FDA has issued regulations reflecting section 360k(a)'s narrow reach. *See generally* 21 C.F.R. Part 808; *see Lohr*, 470 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation[.]"). For instance, FDA regulations require that for an FDA requirement to have preemptive effect, it must establish a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. § 808.1(d). Likewise, to be preempted, state-law requirements must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* § 808.1(d)(1).

B. The Decision in *Medtronic v. Lohr.*

In *Lohr*, plaintiff Lora Lohr and her husband Michael Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its section 510k "substantial equivalence" process. *See supra* note 1. This Court held that none of the Lohrs' claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

1. *The Majority Opinion.* Although there was a concurrence and a partial dissent in *Medtronic*, the majority opinion contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see Lohr*, 470 U.S. at 480; *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) the Lohrs' design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations is not preempted. *Id.* at 494-97; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that the Lohrs' manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further noted that the Lohrs' damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found that the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the majority held, such claims were outside of the prohibited category of state-law requirements "with respect to" specific devices within the meaning of section 360k(a). *Id.* at 501-02.[2]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He did not join Parts IV and VI of the lead opinion (*see supra* note 2) because he was not convinced that MDA preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, discussed immediately above, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to the Lohrs' claims were not "specific" in any

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[2]Speaking for a four-Justice plurality, the lead opinion relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. 518 U.S. at 488-91 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of the Lohrs' claims was preempted. *Id.* at 502-03.

relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 470 U.S. at 505-06. He noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of the Lohrs' claims. *Id.* at 506.

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and Justices Scalia and Thomas. In her view, state-law damages claims can constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that the Lohrs' design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority that the Lohrs' manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

C. Factual Background and Proceedings Below.

1. This case arose from injuries caused by Medtronic's Model 4004 and 4004M pacemaker leads, among the worst performing leads ever marketed in the United States. A pacemaker lead is a wire that delivers a pacemaker's electrical impulse to the heart. Although the FDA granted PMA to the 4004 and 4004M leads, the FDA later discovered during an inspection that the probability of lead failure was high because a platinum coating intended to prevent degradation of the lead's polyurethane insulation failed to do so. *Goodlin*, 167 F.3d at

1368.[3] The FDA subsequently instructed Medtronic to issue a Health Safety Alert letter informing physicians about the pacemaker's flaw. *Id.* at 1369. In that letter, Medtronic told physicians "to consider whether prophylactic replacement would be appropriate, especially . . . [for] pacemaker-dependent patients." *Id.* The letter said that physicians should replace the pacemaker lead if "the risk of continued use outweigh[ed] the risk associated with implanting a new lead." *Id.*

Petitioners include 14 patients (including the estate of one who later died) who were implanted with 4004 and 4004M leads. Twelve later underwent additional heart surgeries to have their leads replaced, and two had theirs capped. In four separate lawsuits, these Petitioners, along with the spouses of seven of them (also Petitioners here), sued Medtronic in the Southern District of Ohio, alleging claims including strict liability, negligence, negligent misrepresentation, negligence per se, failure to warn, breach of warranty, and misrepresentation. The district court had subject matter jurisdiction based on diversity of citizenship under 28 U.S.C. § 1332(a)(1). The cases were consolidated for pretrial discovery with other cases involving injuries caused by the 4004M lead, and the cases were later stayed during the pendency of the Sixth Circuit's decision in *Kemp v. Medtronic*, 231 F.3d 216 (6th Cir. 2000).

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[3]The 4004 and 4004M leads were approved as "PMA supplements," which allowed Medtronic to change the design of a precursor PMA device, the 4003 lead. The "same procedures and actions" that apply to a PMA apply to a PMA supplement. 21 C.F.R. § 814.39(c). For present purposes, the distinction between approval of an original PMA and a PMA supplement are immaterial.

2. The decision in *Kemp* dictated the outcome of this case. Three aspects of that decision are pertinent here.

First, *Kemp* held that the FDA's approval of Medtronic's PMA application for the 4004M lead, coupled with the FDA's form approval letter, amounted to a specific preemption-triggering federal requirement within the meaning of 21 U.S.C. § 360k(a) and this Court's decision in *Lohr*. 231 F.3d at 226-27. In particular, it construed the FDA's approval of the 4004M PMA application as transforming the information regarding those topics contained in the application into a specific federal requirement. *Id.* at 228. The court thus held that a state-law damages claim based on a device's defective design or manufacture, or based on a claim that the device was accompanied by inadequate warnings, is preempted because of the perceived conflict between the purported federal requirement and the state-law damages claims. The court acknowledged that its holding was flatly at odds with the Eleventh Circuit's decision in *Goodlin*, 167 F.3d 1367, which also involved the 4004M lead and which held that the FDA's premarket approval does not trigger preemption under section 360k(a). 231 F.3d at 225 (noting that *Goodlin* "addressed this exact issue on largely indistinguishable facts"). In reaching its conclusion, the Sixth Circuit did not mention the *Lohr* majority's holding that state-law duties of general applicability, such as those typically relied on in state-law damages claims, are not preempted by section 360k(a). *See Lohr*, 470 U.S. at 501-02.

Second, the court of appeals provided additional explanation for its holding that the Kemps' failure-to-warn claim was preempted by the MDA. The court stated that, because the plaintiffs alleged that Medtronic failed to warn of the malfunctions of the 4004M's insulation prior to Mrs.

Kemp's injuries, "the claim was premised on the [in]adequacy of the warnings reviewed and approved by the FDA." 231 F.3d at 236. Thus, in the Sixth Circuit's view, this claim was preempted because it would impose a requirement different from that imposed by the FDA. In this regard, the court did not address, or even cite, the FDA regulation permitting a manufacturer to make label changes and provide additional warnings to enhance safety of PMA devices without prior FDA approval. *See* 21 C.F.R. § 814.39(d)(1) & (2) (cited as support for majority holding in *Lohr*, 470 U.S. at 497 n.16).

Third, the Sixth Circuit held that the plaintiffs' negligence per se claim was preempted. That claim was based on plaintiffs' assertion that the FDA required a platinum coating of a specific uniform thickness. Because the Sixth Circuit found that the FDA had not imposed such a requirement, it held that the plaintiffs' claim would impose a requirement "different from and in addition to" the federal requirements for the device. *Kemp*, 231 F.3d at 230-32.

3. After the Sixth Circuit decided *Kemp*, Medtronic moved for summary judgment in each of Petitioners' cases. Petitioners sought to amend their complaints to allege causes of action that would be viable under *Kemp*'s analysis—claims such as (1) post-sale failure to warn, (2) post-sale failure-to-recall, (3) failure to comply with federal requirements that mirrored state requirements; and (4) negligence per se in failing to comply with the FDA's conditions of approval. The amended complaints also included causes of action for strict liability, negligence, and breach of warranty. The district court held that all claims except for (3), above, are preempted. Pet. App. 24a.

The district court gave Petitioners 10 days in which to amend their complaints to include only the one claim that it did not find preempted. The court then consolidated the cases for all purposes under *Cupek v. Medtronic*.[4] Instead of filing a new complaint, Petitioners moved for reconsideration. While that motion was pending, the parties jointly requested a stay pending settlement discussions. After the stay was lifted, the court denied the motion for reconsideration and, then, citing the passage of time since the court's initial order granting leave to amend, denied Petitioners' request for leave to amend their complaint. *Id.* 25a. The court then granted summary judgment to Medtronic. *Id.* 30a.

Relying largely on *Kemp*, the Sixth Circuit affirmed. *Id.* 5a-7a. Further, the court rejected Petitioners' request that the court of appeals revisit *Kemp*. *Id.* 7a.

REASONS FOR GRANTING THE WRIT

Eight years ago, this Court considered a petition for certiorari that raised the same question presented here. *See Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998). Responding to the Court's request for advice on the petition, the Solicitor General agreed with the plaintiffs in the case that PMA does not preempt state-law damages claims. *See* Brief of the United States As Amicus Curiae in *Kernats* 14-18 (filed Dec. 1997). Although the Solicitor General recommended against granting certiorari in that case—for reasons inapplicable here—he noted that "[t]he

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[4] The case was named for Ethel Cupek, the first-named plaintiff in one of the four original cases, although she was voluntarily dismissed from the case in September 1998.

current division among the lower courts . . . would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." *Id.* at 18.[5]

Since the Solicitor General's filing in *Kernats*, the division among the lower courts, and thus the need for this Court's guidance, has become even more pronounced. Adding to the confusion, the United States, in a letter brief filed in a Third Circuit case, *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004), reversed the government's position, making an argument that, by its own admission, contradicts the argument it made to this Court in *Kernats*. *See id.* at 177-78 (describing brief). The government's flip-flop heightens the already "strong justification for this Court to grant review and definitely resolve" the question presented.

A. The Federal And State Appellate Courts Are Deeply Divided Regarding The Application Of *Medtronic v. Lohr* To The Question Presented.

The decision below reflects the division among the federal and state appellate courts on the issue that was determinative in the court below: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly

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[5]The Solicitor General argued that the petition should be denied because the Court did not have jurisdiction to review the state appellate court decision, which was not final under 28 U.S.C. § 1257, because the lower court's holding that PMA did not preempt damages claims was correct, and because of the pendency of a proposed FDA interpretive rule (later withdrawn) regarding preemption.

design and manufacture the device and failed to warn of the device's risks. Some courts, such as the Eleventh Circuit, have held that PMA does not trigger preemption under section 360k(a) and that, therefore, state-law damages actions alleging injuries caused by PMA devices are not preempted. Other courts, such as the Sixth Circuit, have held that PMA does trigger preemption. *Compare, e.g., Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004) (preemption); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (same); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (same), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997).

Moreover, as noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. § 808.1(d). Among the federal and state appellate courts, however, conflicts exist with respect to both prongs of *Lohr*'s analytic framework.

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. § 360k(a), a federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. § 801.430), in contrast to the comprehensive, but general, good manufacturing and labeling regulations that the Court held did not have preemptive effect. 470 U.S. at 497-99.

The FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner. Accordingly, several courts have held that the PMA process does not constitute a device-specific requirement for purposes of preemption under section 360k(a). *See Goodlin*, 167 F.3d at 1373-77; *Weiland*, 721 N.E.2d at 1152-53; *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997).

Several other courts have come to the opposite conclusion. *See, e.g., Horn*, 376 F.3d at 169; *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887-88 (Cal. App. 1997).[6]

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[6]Similarly, two state Supreme Courts have held that state-law damages claims involving class III devices marketed under the MDA's investigational device-approval process (*see* 21 U.S.C. § 360j(g))—which is often a precursor to the PMA process—are not preempted because that process does not establish specific requirements under *Lohr*. *See Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997). *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997), *cert.*

(continued...)

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Fifth Circuit, for example, has simply ignored *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. *See Martin*, 254 F.3d at 582-83. Other post-*Lohr* courts that have found damages claims preempted have dealt with the issue more directly, acknowledging *Lohr*'s majority holding and noting that it would, if applied in those cases, require a ruling in favor of the plaintiff. *See, e.g., Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). Those courts have not followed this portion of the majority opinion, however, on the ground that it is purportedly incompatible with Justice Breyer's concurrence. *Horn*, 376 F.3d at 174-75; *Papike*, 107 F.3d at 742; *Mitchell*, 126 F.3d at 912; *see also Steele*, 63 Cal. Rptr. at 887; *Fry*, 695 A.2d at 517.

These rulings are at odds with the decisions of other appellate courts that have held that this Court meant what it said in *Lohr*. State laws of general applicability are not among those laws targeted for preemption by section 360k(a). *See Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997); *State ex rel Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004) (no preemption of claim against device manufacturer brought under state consumer fraud statute because statute not limited

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[4](...continued)
denied, 522 U.S. 1075 (1998) (investigational device process does establish preemptive federal requirements). *See also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and stating that PMA and investigational processes are comparable).

to devices); *Niehoff*, 950 S.W.2d at 822 (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker*, 552 N.W.2d at 686 (same); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997) (same), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997) (same), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div.), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App.) ("[P]laintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt."), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996) (same), *review denied*, 1997 Cal. Lexis 833 (Cal. 1997).

For instance, in *Oja*, the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement device. The Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead,

> Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

111 F.3d at 789 (quoting *Lohr*, 470 U.S. at 501) (internal citations omitted).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.[7]

B. The Sixth Circuit's Holdings Cannot Be Reconciled With *Lohr*.

Review should also be granted because the Sixth Circuit's and other appellate courts' misinterpretation of *Lohr* leaves consumers injured by PMA devices without a damages remedy in many parts of the country. The decisions holding that PMA preempts damages claims err in three fundamental ways.

First, the granting of PMA imposes no device-specific requirement triggering preemption of damages claims under section 360k(a). Although the PMA process is often more

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[7] The split in authority is particularly problematic in Illinois and Kentucky, where, if the complaint is filed in or removed to federal court, the plaintiff's claims are preempted, *see Mitchell*, 126 F.3d 902 (7th Cir.); Pet. App. 1a; *Kemp*, 231 F.3d 216 (6th Cir.), but if the complaint is litigated in state court, there is no preemption. *See Weiland*, 721 N.E.2d 1149 (Ill.); *Niehoff*, 950 S.W.2d 816 (Ky.).

rigorous than the marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences), it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed, manufactured, or labeled. As the Eleventh Circuit has explained, although the PMA process "differs in significant ways from the 510k process at issue" in *Lohr*, the result regarding preemption is the same: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Goodlin*, 167 F.3d at 1374, 1376; *see id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus also not preemptive).

Thus, the PMA process contains no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. § 801.420), or to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 470 U.S. at 504. Moreover, the PMA process itself does not impose specific federal "requirements" because the device's specifications originate with the manufacturer, not with the FDA. *Cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) (preemption clause of Airline Deregulation Act does not shelter airlines from lawsuits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings").

Second, the decisions finding preemption of traditional damages claims involving PMA devices misapprehend *Lohr* because such claims are, without dispute, premised on state-law duties of general applicability. *See Lohr*, 470 U.S. at 501-02. Of particular importance, the court of appeals did not mention,

in either the decision below or the *Kemp* decision, the FDA's longstanding preemption regulation, 21 C.F.R. § 808.1, although that regulation is directly applicable here. Section 808.1, which was accorded substantial weight in *Lohr*, 470 U.S. at 496; *see id.* at 505-06 (Breyer, J., concurring), provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices . . . ." 21 C.F.R. § 808.1(d)(1). The FDA's regulation encompasses Petitioners' traditional state-law claims.

Third, many of the courts of appeals have held that PMA preempts traditional damages claims only by disregarding the *Lohr* majority's analysis and focusing on Justice Breyer's concurrence. *See, e.g.*, *Horn*, 376 F.3d at 174-76; *Mitchell*, 126 F.3d at 912. Yet the holdings of those courts are in fact inconsistent with the concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 470 U.S. at 504 (Breyer, J., concurring). Petitioners' state-law damages claims, however, based on general state-law duties to properly design and manufacture a product and to warn of its risks, do not involve a specific state-law requirement of this kind, and thus their claims do not present the kind of direct conflict that concerned Justice Breyer.

In any event, even if the concurrence offered a different analytical approach to assessing the scope of section 360k(a), a lower court has no warrant to disregard a majority holding of this Court. Federal circuit courts are bound to adhere to the

controlling decisions of the Supreme Court. *Hutto v. Davis*, 454 U.S. 370, 375 (1982). As Justice Rehnquist has stated: "[U]nless we wish anarchy to prevail within the federal judicial system, a precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those courts may think it to be." *Id.; see also Thurston Motor Lines v. Jordan K. Rand, Ltd.*, 460 U.S. 533, 535 (1983) ("Needless to say, only this Court may overrule one of its precedents."). Under basic principles of stare decisis, a separate concurrence, regardless of its content, is not a basis for disregarding a majority opinion of the Supreme Court of the United States. *See Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001) (concurrence does not alter meaning of majority opinion); *Maryland v. Wilson*, 519 U.S. 408, 413 (1997) (concurring opinion does not establish precedent); *see also Agostini v. Felton*, 521 U.S. 203, 217 (1997) (case law not affected by views of five Justices in concurring opinions).

By elevating Justice Breyer's concurrence above the majority opinion, decisions such as *Horn*, *Mitchell*, and the cases cited *supra* at p. 17, flout the Court's instruction concerning the weight to be given to concurring opinions, and indeed with the hierarchy of our federal court system. To take one of the more glaring examples, in *Horn*, the majority opinion conceded that the plaintiff's state-law claims were based on "general requirements stemming from state common law," 376 F.3d at 173, that "are not specific 'with respect to'" the particular model of heart pump at issue or even heart pumps generally. *Id.* at 174. Further, it recognized that the *Lohr* plaintiffs had sued "for essentially the same claims Horn has brought," *id.*, and that "*Lohr* concluded that these claims 'escape[] pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that

§ 360k envisioned to be "with respect to" specific devices such as pacemakers.'" *Id.* (quoting *Lohr*, 518 U.S. at 502).

Nonetheless, the *Horn* majority declined to follow the majority opinion of the Court in *Lohr* because it read Justice Breyer's concurrence to mean something different from the majority's holding. *Id.* In fact, the Third Circuit went so far as to say that Justice Breyer's concurrence effectively negates the fact that he expressly joined in this aspect of the majority holding. *Id.* It then recast Justice Breyer's vote in *Lohr* to transform the four-Justice dissent into a five-Justice majority on this point. *Id.* at 176. Indeed, the opinion repeatedly refers to the holdings of the *Lohr* **majority** as the statements of a **plurality**. *See, e.g., id.* at 174, 175, 176; *see also id.* at 184 (Fuentes, J., dissenting) (highlighting error of majority's approach). Although Justice Breyer provided the "fifth vote" for the holding that state-law claims based on duties of general applicability are outside the scope of preemption, the *Horn* majority declared that vote a nullity: "This was not a principle that received Justice Breyer's agreement." *Id.* at 175.

Because Justice Breyer joined in the holding of *Lohr*, thereby forming a majority, the Third, Seventh, and Ninth Circuits, in *Horn*, *Mitchell*, and *Papike*, have overstepped their authority and "ignored, consciously or unconsciously, the hierarchy of the federal court system created by the Constitution and Congress." *Hutto*, 454 U.S. at 375. As the Tenth Circuit recognized in *Oja*, 111 F.3d at 788 n.3, the five-justice majority opinion is the binding precedent established in *Lohr*. The petition should be granted for this reason as well.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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June 2005

United States Court of Appeals
for the Sixth Circuit

ETHEL CUPEK, et al.,
Plaintiffs-Appellants,

v. No. 04-3201.

MEDTRONIC, INC.,
Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 97-00105—Sandra S. Beckwith, Chief District Judge.

Argued: March 10, 2005
Decided and Filed: April 21, 2005

Before: KENNEDY, MOORE, and SUTTON, Circuit Judges

OPINION

KENNEDY, Circuit Judge. Plaintiffs appeal the district court's denial of leave to amend their complaint in this product liability action and the grant of summary judgment to Defendant Medtronic, Inc. based on this court's earlier decision in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir.2000), dismissing similar claims. We affirm the district court.

BACKGROUND

Plaintiffs collectively sued Defendant alleging defects in Defendant's pacemaker leads implanted in them or their spouses. Their cases were consolidated with *Kemp v.*

Medtronic, Inc., No. C-1-97-103, 1999 (N.D. Ohio June 27, 1997) for the purposes of discovery. After all cases were consolidated in the Southern District of Ohio and after the district court denied Plaintiffs class certification, consolidation for trial, and permissive joinder, the parties agreed to administratively close all claims save *Kemp*. That case was fully litigated and appealed. *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir.2000) (denying the bulk of Plaintiffs' claims due to federal preemption), *rehearing and rehearing en banc denied*, No. 99-3720, 2001 WL 91119 (6th Cir. Jan. 26, 2001) (unpublished), *and cert. denied*, 534 U.S. 818 (2001).

After resolution of the *Kemp* case, Plaintiffs filed a motion to reinstate their actions and file an amended complaint to present new causes of action that federal law does not preempt, and to raise arguments that are distinguishable from the arguments made in *Kemp*. Defendant did not oppose reopening the case and moved the court to grant it summary judgment pursuant to a motion it had earlier filed at the conclusion of the *Kemp* appeal.

Plaintiffs' proposed amended complaint comprised eight counts. Counts I and II alleged post-sale "failure to warn" and post-sale "failure to recall" claims against Defendant based on "information learned after FDA review of the Model 4004 4004M PMA Supplement Applications."[1] Count III alleged that Defendant failed "to [c]omply with [f]ederal [r]equirements [c]onsistent with [s]tate [r]equirements." ("Medtronic failed to comply with applicable CFR regulations in its Model 4004 4004M PMA Supplement applications.").

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[1] Paragraphs 41 and 48 of these two counts read: "These duties are independent of any obligation a manufacturer may have to comply with applicable federal regulations."

Count IV alleged Defendant's "Negligence Per Se" in its "failure to comply with the [Food and Drug Administrations's (FDA)] conditions of approval." Counts V through VIII reasserted claims originally plead by Plaintiffs in their original complaint with greater factual specificity.

The district court disposed of Plaintiffs' motion to amend in three separate opinions and then granted summary judgment to Defendant in a final opinion. In the first opinion, issued on December 10, 2001, the district court found that counts V through VIII were directly precluded by *Kemp*. It also found that count IV was preempted because it was, in essence, a disguised fraud on the FDA claim. The district court found that federal law preempts such claims (citing *Kemp* and *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348 (2001)). The district court additionally found that counts I and II were preempted by federal law because they would impose state requirements "different from" or "in addition to" federal requirements, thus making them futile claims. The court did, however, find that federal law did not preclude Plaintiffs' proposed count III. It granted Plaintiffs ten days to file an amended complaint alleging that sole claim.

Plaintiffs failed to file the required amended complaint within the allotted time and, instead, on January 14, 2002, requested that the court reconsider its decision. Before the court ruled on that motion, the parties requested a stay to allow them to engage in settlement discussions. The court granted the stay. After lifting the stay, on November 11, 2002, the district court denied Plaintiffs' request to reconsider its earlier decision. On December 13, 2002, Plaintiffs then requested leave to amend their complaint to allege the claim the court had previously allowed.

In its third opinion, filed on September 10, 2003, the district court denied Plaintiffs leave to amend their complaint, as previously allowed, holding that justice did not require granting Plaintiffs leave at that time, because of the opportunities given them to amend their complaint in a more timely fashion. The district court also expressed concern that Defendant would be unduly prejudiced were it to grant Plaintiffs leave to amend in view of how much time had elapsed since Plaintiffs filed their original complaint. The district court also directed Plaintiffs to show cause why it should not grant Defendant's motion for summary judgment. Finally, on January 13, 2004, after Plaintiffs filed a response to the show cause order, the district court granted summary judgment to Defendant on the remaining claims. This appeal followed.

On appeal, Plaintiffs allege three errors. First, Plaintiffs claim that the district court erred in denying them leave to amend their complaint to allege that Defendant was negligent per-se in failing to comply with the FDA's conditions of approval (count IV of the proposed amended complaint). Second, Plaintiffs allege that the district court erred in denying them leave to amend their complaint to assert Defendant's post-sale failure to warn and post-sale failure to recall claims (counts I and II of the amended complaint). Finally, Plaintiffs request that this court revisit its holdings in *Kemp* (and consequently reverse the district court's denial of leave to amend for counts V through VIII). Plaintiffs did not appeal the district court's denial of leave to amend count III of the proposed amended complaint.

ANALYSIS

We review de novo the district court's determination that granting Plaintiffs leave to amend would be futile. *See*

Ziegler v. IBP Hog Market, 249 F.3d 509, 518 (6th Cir.2001). We do not find error in the district court's decision. Granting leave to amend on count IV would be futile because that count is a disguised fraud on the FDA claim. The Supreme Court and this court held that federal law preempted such claims. *See Buckman,* 531 U.S. at 347-48 (explaining that the usual presumption against preemption does not apply where the field of law is inherently federal and stating that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"); *id.* at 349 n. 4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.") (quoting 21 U.S.C. § 337(a)); *Kemp,* 231 F.3d at 236.

Federal law also preempts proposed amended counts I and II because those counts would impose state requirements "different from" or "in addition to" the federal requirement. *See* 21 U.S.C. § 360k(a) ("no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."). As recognized in *Kemp,* the FDA requires continuous updates as part of the pre-market approval (PMA) application and supplement process. *Kemp,* 231 F.3d at 221-22. These updating requirements specifically address warnings and recalls associated with medical devices. *See* 21 U.S.C. § 360h(a) (giving the Secretary of Health and Human

Services the authority to issue or withhold warnings concerning medical devices based on the Secretary's assessment of the risks); *id.* § 360(e)(1) (giving the Secretary authority to order manufac-turers to cease distributing devices upon a finding they could cause "serious, adverse health consequences or death"); *id.* § 360h(e)(2)(a) (giving the Secretary authority to issue recall orders); 21 C.F.R. § 803.50 (requiring device manufacturers to report adverse medical device events to the FDA); *id.* § 810.10 (giving the FDA discretion to determine if a recall is necessary and to decide to delay public notification to avert health risks). Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the PMA supplement process would constitute state requirements "different from" or "in addition to" the requirements of the federal PMA application and supplement process. *See* 21 U.S.C. 360k(a); *see also Kemp,* 231 F.3d at 235. Such requirements would, therefore, not "parallel federal safety requirements ...." *Buckman,* 531 U.S. at 353.[2] Plaintiffs' proposed amended claims themselves undermine their preemption arguments, because those claims assert that Defendant has duties "independent of any obligations ... to comply with applicable federal regulations." Such independent duties are, at the very least, "in addition to" federal requirements, and may very well be "different from" federal requirements. Thus, federal law preempts proposed amended counts I and II because those counts would require Defendant to comply with state requirements "different from"

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[2]There appears to be significant disagreement between the parties over whether Minnesota or Ohio law applies to this dispute. That question is irrelevant to our disposition of these issues. Federal law would preempt Plaintiffs' claims regardless of whether Minnesota or Ohio law applied.

or at least "in addition to" federal requirements. Plaintiffs' request to amend was futile.

Finally, Plaintiffs ask us to revisit our holding in *Kemp*. We may not do so. "A panel of this Court cannot overrule the decision of another panel. The prior decision remains controlling authority unless an inconsistent decision of the United States Supreme Court requires modification of the decision or this Court sitting en banc overrules the prior decision." *Salmi v. Secretary of Health and Human Services*, 774 F.2d 685, 689 (6th Cir.1985). Plaintiffs cite no authority that would allow us to revisit this court's earlier holding. We hold, therefore, that the district court did not err in denying Plaintiffs leave to amend, because the proposed amendments are futile as described by the district court, this court in *Kemp*, and the Supreme Court in *Buckman*.

CONCLUSION

For the foregoing reasons, we **AFFIRM** the decision of the district court.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethel Cupek, et al.	)	
Plaintiffs,	)	Case No. C-1-97-105
	)	
vs.	)	
	)	
Medtronic, Inc.,	)	
Defendant.	)	

ORDER

This matter is before the Court on Plaintiffs' Motion to Reinstate Litigation and Motion for Leave to File An Amended Complaint (Doc. No 32). For the reasons set forth below, Plaintiffs' Motion to reinstate the litigation is well-taken and is GRANTED; Plaintiffs' motion to file an amended complaint is GRANTED IN PART AND DENIED IN PART.

I. Procedural Background

Plaintiffs in this case were implanted with heart pacemaker devices which employed either 4004 or 4004M pace maker leads manufactured by Defendant Medtronic, Inc. ("Medtronic"). A pacemaker lead sends an electrical current to the heart in order to sense and correct irregular heartbeats. Medtronic is a Minnesota corporation with its principal place of business located in Minneapolis, Minnesota. Plaintiffs are all citizens of states other than Minnesota. The subject matter jurisdiction of this Court is founded upon diversity pursuant to 28 U.S.C. § 1332.

On January 24, 1997, Plaintiffs filed a complaint (Doc. No.1) against Medtronic under state last for strict products liability (Count I), negligence and negligent misrepresentation (Count II), negligence per se (Count III), failure to warn (Count IV), breach of implied warranties (Count V), breach of express warranties (Count VI), fraudulent misrepresentation (Count VII), intentional infliction of emotional distress (Count VIII), negligent infliction of emotional distress (Count IX), fear of future product failure (Count X), and loss of consortium (Count XI). The general theory espoused by Plaintiffs was that the pacemaker leads were defective in terms of their design, manufacture, and accompanying warnings, that Medtronic knew they were defective when it marketed them, that, essentially, Medtronic defrauded the Food and Drug Administration into approving the leads for use.

On May 27, 1999, the Court entered an order (Doc. No. 28) administratively closing this case without prejudice to reopen pending the resolution of an appeal taken by the plaintiff in Kemp v. Medtronic, Inc., C-1-97-103 (S.D. Ohio) (Beckwith, J.). The Kemp case presented claims against Medronic identical to the ones asserted here with regard to the 4004M pacemaker lead. Understanding the procedural history of the Kemp is case is critical to resolving the motions pending in this case. Therefore, the Court will devote substantial time and space explaining the issues and outcome of Kemp.

In Kemp, the Court ruled on two separate motions for summary judgement filed by Medtronic. In its first motion for summary judgment, Medtronic argued that Mrs. Kemp's state law claims were preempted by the Medical Device Amendments ("MDA"), 21 U.S. C. § 360k, to the Food, Drug, and Cosmetic Act. The MDA preempts any state law requirement which is different from or in addition to any requirement imposed by the Act. The main issues presented on

the first motion for summary judgment were whether the FDA's premarket approval ("PMA") and PMA supplement process, under which Medtronic obtained approval to market the 4004m lead, established any specific federal requirement under the Act with respect to the lead, and, if so, whether a state law judgment in Mrs. Kemp's favor on any of her claims would impose a state requirement different from or in addition to the federal requirement.

In answering the questions presented, the Court found that the PMA Supplement process established specific federal requirements relative to the 4004M lead. Therefore, Mrs. Kemp's claims would be preempted if judgment on her claims would impose requirements different from or in addition to the federal requirements. The Court then found that claims based on defective design, defective warning, and non-conformance to warranties were preempted because the claims would impose additional or different requirements than the federal requirements. With respect to the manufacturing defect claim, the Court held that a claim for negligence despite adherence to FDA standards was preempted, but that a claim for negligent adherence to the standards imposed by the PMA was not preempted. The Court noted, however, that Mrs. Kemp had not asserted a claim for negligent adherence to the PMA requirements. The Court did, however, grant leave for Mrs. Kemp to file amended complaint which alleged that her 4004M lead deviated from the specifications approved by the FDA in the PMA and PMA Supplement. Rounding out the order, the Court ruled that Mrs. Kemp's state law claim for fraud on the FDA was preempted by federal law. See generally Kemp v. Medtronic, C-1-97-103 (S.D. Ohio Jan. 12, 1999) (Doc. No. 159).

Following the Court's ruling on summary judgment, Mrs. Kemp filed an eight count amended complaint. At a

pretrial hearing, the Court granted Medtronic's motion for judgment on the pleadings on five counts and partially granted the motion on one other count on the grounds the claims asserted therein were essentially restatements of claims the Court had previously ruled were preempted by federal law. What remained after granting the motion for judgment on the pleadings were claims for negligence per se and strict liability based on Medtronic's alleged failure to build the 404M lead in conformity with FDA specifications and a derivative state law claim for loss of consortium.

The parties then filed a cross-motions for summary judgment on the remaining claims. Mrs. Kemp's theory of the case was that the PMA specifications required Medtronic to coat the 4004M lead with 500 angstroms of platinum sputtering in order to prevent metal induced oxidation ("MIO"), that Medtronic did not coat the lead with 500 angstroms of platinum sputtering, and that this omission caused her lead to fail. The Court ruled, however, that while the PMA required Medtronic to coat the lead with platinum sputtering, the PMA did not require a particular thickness of sputtering. Therefore, Plaintiff's claim was preempted because it would impose a requirement different from or in addition to the PMA requirements. Furthermore, it was undisputed in the case that the lead did in fact have a platinum sputter coating. As a consequence, the Court granted Medtronic's motion for summary judgment, and denied Mrs. Kemp's motion for summary judgment, as to the negligence per se and strict liability claims. The Court also granted Medtronic's motion for summary judgment on the loss of consortium claim on the grounds that it was derivative of the other claims. See id. Doc. No. 211.

Mrs. Kemp then filed an appeal of this Court's judgment to the Sixth Circuit Court of Appeals. On November

1, 2001, the Sixth Circuit issued an opinion affirming the judgment of this Court in all respects. See Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000) ("Kemp I"). The Court first found that the PMA and PMA Supplement process impose specific federal requirements applicable to the device. See id. at 227-28. The Court next found that although a claim that the lead did not conform to FDA specifications established through the specifications established through the PMA process was not necessarily preempted, it too rejected Mrs Kemp's argument that the PMA Supplement required 500 angstroms of platinum sputtering. Therefore, the Court found, the negligence per se claim was preempted by federal law. Id. at 230-32. The Court next found that state law claims for fraudulent misrepresentation and fraud on the FDA are preempted by federal law. Id. at 232-36.

The Court next ruled that state law claims for failure to warn based on the alleged inadequacy of warnings approved by the FDA are preempted by federal law. See id. at 236. In relation to this claim, Mrs. Kemp argued that Medtronic negligently failed to warn of defects it became aware of after receiving FDA approval. The Court ruled, however, that Mrs. Kemp presented that argument for the first time on appeal and that, therefore, it could not property address that claim. See id. at 237. Accordingly, the Court declined to decide whether federal law preempted a failure to warn claim based on information obtained subsequent to FDA approval of the device. Id. The Court then issued a second, unpublished, opinion on Mrs. Kemp's petition for rehearing which reiterated that state law claims based on alleged failure to comply with federal regulations and FDA conditions of approval are preempted by federal law. See Kemp v. Medtronic, Inc., No. 99-3720, 2001 WL 91119, at *1 (6th Cir. Jan. 26, 2001) ("Kemp II"). In addition, the Court rejected Mrs. Kemp's

contention that the Court improperly refused to consider her post-FDA approval failure to warn claim. See id. at *2.

Following the issuance of the opinion in Kemp I, Medtronic filed a motion to lift the stay in this case and simultaneously moved for summary judgment on Plaintiffs' claims based on the decision in Kemp I, and the arguments it presented to this Court in its briefs in that case. See Doc. No. 29. Plaintiffs initially opposed Medtronic's motion to lift the stay because the Kemp appeal was not finalized due to the pending petition for rehearing en banc and planned petition for writ of certiorari to the U.S. Supreme Court. Subsequently, however, the parties filed a stipulation continuing the stay pending final resolution of the Kemp appeals process. See Doc. No. 31. As noted above, the Sixth Circuit denied Mrs. Kemp's petition for rehearing en banc on January 26, 2001. On October 1, 2001, the Supreme Court denied Mrs. Kemp's petition for a writ of certiorari. See Kemp v. Medtronic, Inc., 122 S. Ct. 48 (2001).

On October 4, 2001, Plaintiffs in this case filed the present motions to reinstate this case to the active docket and for leave to file an amended complaint. Plaintiffs attached a copy of the proposed amended complaint to their motion. Medtronic does not oppose the motion to reinstate the case, but only for purposes of ruling on its pending motion for summary judgment. Medtronic opposes Plaintiffs' motion to amend the complaint principally on the grounds that granting leave to amend would be futile.

II. The Proposed Amended Complaint

Plaintiffs seek leave to file an amended complaint in order to, inter alia, "clarify certain post-manufacture failure to warn/failure to recall claims based on information obtained by

Medtronic post-FDA approval." See Doc. No. 32, at 1. In addition, Plaintiffs contend "that the Sixth Circuit wrongly decided the Kemp appeal." Id. Therefore, Plaintiffs assert claims rejected in the Kemp decision in order to preserve those claims to argue on appeal for a modification or reversal of existing law or the establishment of new law. See id. at 1-2. The proposed amended complaint contains eight counts consisting of four "new" claims and four "old" claims.

Count I of the proposed amended complaint asserts a claim for failure to warn based on information learned after FDA review and approval of the 4004 and 4004M leads. Specifically, this count alleges that Medtronic had a continuous duty to warn after its pacemaker lead was sold to a customer which is independent of any applicable federal regulations. Count I alleges that the duty required Medtronic to issue new or additional warnings based on new or additional information that would have caused a reasonable manufacturer to amend existing warnings. Count I further alleges that following FDA approval of the 4004 and 4004M leads, Medtronic obtained information which indicated that MIO would cause the leads to fail prematurely but that Medtronic continued to manufacture, market, and sell the leads without issuing additional warnings.

Count II of the proposed amended complaint states a claim for negligent failure to recall and/or withdraw the 4004 and 4004M leads from the market based on information obtained after FDA review and approval of the leads. This count alleges that a manufacture has an ongoing and continuous duty to recall a product from the market and/or cease manufacturing and selling the product when it learns that the product is dangerous and can cause injury when used in a foreseeable or intended manner. Count II alleges that this duty is independent of any other federal regulations. Count II further alleges that Medtronic breached this duty by not

recalling the 4004 and 4004M leads after obtaining information indicating that the leads would fail and not perform as intended.

Count III of the proposed amended complaint asserts a claim for negligence per se based on failure to comply with federal requirements consistent with state requirements. Count III alleges that Medtronic failed to comply with unspecified applicable CFR regulations in it 4004/4004M PMA Supplement applications. Count III further alleges that by approving the 4004/4004M, the FDA established additional requirements for the design and manufacture of the leads and that Medtronic failed to manufacture the leads as required by the FDA.

Count IV of the proposed amended complaint alleges that in submitting the PMA Supplement applications for the 4004 and 4004M leads, Medtronic was obligated to comply with the FDA conditions of approval set forth in 21 C.F.R. § 814.84. Count IV then states a number of ways in which Medtronic allegedly violated the FDA's conditions of approval. Count IV alleges that Medtronic's alleged failure to comply with 21 C.F.R. § 814.84 invalidated the FDA's approval of the leads. The apparent theory of this claim is that it the FDA's approval of the leads was invalid, then there are no specific federal requirements applicable to the leads, and hence, no preemption of state law claims.

Finally, as noted above, Counts V through VIII of the proposed amended complaint assert claims which Plaintiffs admit are precluded by the current law of this Circuit. Plaintiffs argue, however, that the applicable law was wrongly decided and state that they intend to ask for a reversal or modification of existing law on appeal.

III. Motion to Amend Standard

Rule 15 (a) of the Federal Rules of Civil Procedure provides:

> A party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served or, if the pleading is one to which no responsive pleading is permitted and the action has not been placed upon the trial calendar, the party may so amend it at any time within 20 days after it is served. Otherwise a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires.

Fed. R. Civ. P. 15 (a). As the Rule points out, leave to amend shall be freely granted. The thrust of the provision "is to reinforce the principle that cases should be tried on their merits rather than on the technicalities of pleadings." Tefft v. Seward, 689 F.2d 637, 639 (6th Cir. 1982). Delay that is not intended to harass the defendant is not in itself a permissible reason to refuse leave to amend. Id. at 639 n.2. Furthermore, there must be " at least some significant showing of prejudice to the opponent" if the motion is to be denied. Moore v. City of Paducah, 790 F.2d 557, 562 (6th Cir. 1986). The case law of this Circuit manifests " liberality in allowing amendments to a complaint." Id. Absent undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, or if allowing the amendment would be futile, a court should grant leave to amend. Thiokol Corp. v. Department of Treasury, 987 F.2d 376, 383 (6th Cir. 1993) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)). For purposes of Rule 15(a), an amendment

is futile if it would not withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. See Rose v. Hartford Underwriters Ins. Co., 203 F.3d 417, 420 (6th Cir. 2000).

IV. Analysis

In its brief opposing the motion for leave to amend, Medtronic does not argue that undue delay, bad faith, or dilatory motive accompanies Plaintiffs' motion. Similarly, Medtronic does not argue that it will suffer undue prejudice if Plaintiffs are permitted to amend their complaint. Therefore, whether the Court should grant leave to amend will depend upon whether the claims asserted in the proposed amended complaint are futile.

Medtronic suggests, however, that it would not be an abuse of discretion for the Court to address its pending motion for summary judgment before considering whether Plaintiffs should be allowed to amend their complaint. Despite this argument, Sixth Circuit precedent suggests otherwise. In Marks v. Shell Oil Co., 830 F 2d 68 (6th Cir.1987), the Court held that the district court abused its discretion by granting a motion for summary judgment based on the original complaint. See id. at 70. Therefore, the Court will address Plaintiffs' motion for leave to amend before issuing any ruling on the pending motion for summary judgment.[3]

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[3]This action is of course appropriate despite Medtronic's contention that Plaintiffs have already pled some of their proposed claims, albeit perhaps unclearly, in the original complaint. In Marks, the Court noted that the proposed amended complaint "expanded considerable upon the original complaint's claims of wrongful nonrenewal of the franchise

The Court starts the analysis by setting forth the Rule 12(b)(6) standard of review. A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. In its consideration of a motion to dismiss under Rule 12(b)(6), the court is required to construe the complaint in the light most favorable to the Plaintiff and accept all well-pleaded factual allegations in the complaint as true. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) and Roth Steel Products v. Rhodes Corp., 705 F.2d 134, 155 (6th Cir. 1983). A court, however, will not accept conclusions of law or unwarranted inferences which are presented as factual allegations. Blackburn v. Fisk University, 443 F.2d 121, 124 (6th Cir. 1974). A court will, though, accept all reasonable inferences that might be drawn from the complaint. Fitzke v. Shappell, 468 F.2d 1072, 1076-77 n.6 (6th Cir. 1972).

The Court addresses the proposed amendment somewhat in reverse fashion in order to dispose first of those claims which clearly are futile. As noted Plaintiffs essentially admit that Counts V through VIII are precluded by existing case law. Plaintiffs, however, believe that the controlling case law was wrongly decided and, therefore, intend to argue for a change of law before the Court of Appeals. This Court, of course, is in no position to tell the Sixth Circuit that its opinion in Kemp was wrong even if it were inclined to do so, which it is not. It is clear, however, that because current case law

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under the [Petroleum Marketing Practices Act]," see id. at 69, but nonetheless held that the district court should have considered the motion to amend before granting summary judgment. Therefore, according to Marks, even if Plaintiffs' proposed amended complaint only clarifies imperfectly pled claims, this Court should still consider the motion to amend before ruling on a motion for summary judgment.

precludes the claims asserted in Counts V through VIII, these counts fail to state claims for relief. Therefore, amending the complaint to include these claims would be futile. Accordingly, the Court would not permit Plaintiffs to file an amended complaint reasserting these claims.

Court IV of the proposed amended complaint also clearly asserts a futile claim. As indicated above, Count IV basically alleges that Medtronic was negligent per se in failing to comply with the FDA's conditions of approval set forth in the Code of Federal Regulations. Even read in the light most favorable to Plaintiffs, this count contains nothing more than a disguised fraud on the FDA claim. As Medtronic correctly points out, not only did the Sixth Circuit reject such a claim in Kemp, the U.S. Supreme Court recently held that a state law claim for fraud on the FDA is preempted by federal law. See Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1017 (2001). As the Supreme Court observed in Buckman, the FDA is amply armed to punish and deter those who do not comply with the applicable regulations. See id. Count IV would interject this Court into the FDA's decision-making processes with the undesirable effect of disrupting the comprehensive scheme which has been established for evaluating and approving medical devices. Accordingly, Count IV is clearly preempted and, therefore, fails to state a claim for relief. Consequently, the Court would not permit Plaintiffs to file an amended complaint containing proposed Count IV.

Whether Counts I through III are futile depends on whether the claims contained therein are preempted by the Medical Device Amendments. A noted above, a state law claim will be preempted by the MDA if would impose a requirement different from or in addition to the federal requirements. See 21 U.S.C. § 360k(a). Counts I and II seek to impose tort liability on Medtronic for its alleged negligent

failure to issue additional warnings and/or recall the 4004 and 4004M leads after the devices had been approved by the FDA upon obtaining information which indicated that the leads posed a health or safety risk. The Court finds that the liability Plaintiffs seek to impose in Counts I and II would constitute a state law requirement different from or in addition to the requirements imposed by the federal law. Therefore, the claims asserted in Counts I and II are preempted.

The Court first observes that the Food, Drug, and Cosmetic Act gives to the Secretary of Health and Human Services authority to issue a notification if a medical device presents a substantial risk of harm to public health. See 21 U.S.C. § 360h(a). This same section, however, gives the Secretary the discretion to withhold notice to individuals if he or she determines that giving notice would present a greater danger to the health of such individuals than no notice at all. See id. § 360h(a)(2). The Secretary is also authorized order [sic] manufacturers to cease distribution of a device upon finding there is a reasonable probability that a medical device intended for human use would cause serious, adverse health consequences or death. See id. § 360h(e)(1). This section further authorizes the Secretary to issue a recall order after providing an opportunity for the manufacturer to be heard. See id. § 360(e)(2).

The FDA has notification and recall authority which substantially parallels that authority given to the Secretary. See generally 21 C.F.R. Pt. 810 (Medical Device Recall Authority). In addition to its recall authority, the FDA has promulgated regulations requiring manufacturers to submit reports of corrections or removals of devices. See 21 C.F.R. § 806.10. Manufacturers are also required to submit to the FDA reports of individual adverse events. 21 C.F.R. § 803.50. Specifically, this section provides:

> Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:
> (1) May have caused or contributed to a death or serious injury; or
> (2) Has malfunctioned and such device or similar device marketed by the manufacture would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F. R. § 803.50 This section states that information is reasonably known to a manufacture if it "can be obtained by analysis, testing or other evaluation of the device." See id. § 803.50(b)(1)(iii). Finally, the regulations provide that the FDA may decide to withhold notice of a mandatory recall if it "determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential." See 21 C.F.R. § 810.18.

What is apparent from reading the applicable statutes and regulations is that Congress and the FDA have established a complex and comprehensive infrastructure for monitoring and ensuring the continued safety and efficacy of approved medical devices. Significantly, despite this comprehensive minoring and reporting scheme, nothing in either the governing statute or the FDA regulations mandates that a manufacturer remove a device from the market or issue additional warnings if it learns or becomes reasonably aware that its medical device may cause or contribute to death or serious injury. This omission appears to be no accident. The Senate Report accompanying

The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990), the legislative enactment which strengthened the Secretary's recall authority, acknowledges that the FDA's reliance on voluntary recalls by manufacturers did not provided the necessary consumer protection where potentially life-threatening devices remained on the market. See S. Rep No. 101-513, §§ I, II(B), III(11) (1990). Despite the awareness of this flaw in the system, however, Congress did not imposed [sic] upon manufacturers a duty to recall defective medical devices. Therefore, where Congress has acknowledge that the voluntary recall system was not completely effective, and has amended the system by imposing reporting requirements, but not recall and notification requirements, the Court must conclude that Congress did not intend for recalls and warnings to be issued in every case where a medical device may have contributed to death or injury. See, e.g., Northwest Airlines, Inc. v. Transport Workers Union of Am., AFL-CIO, 451 U.S. 77, 97 (1981) ("The presumption that a remedy was deliberately omitted from a statute is strongest when Congress has enacted a comprehensive legislative scheme including an integrated system of procedures for enforcement."). Indeed, both the statute and the regulations recognize that in some instances knowing that the device is potentially defective poses a greater risk to health than the defective device itself. In fact, upon receiving the incident reports that manufactures are required to submit, the FDA may well still conclude that the benefits of the device continue to outweigh its risks.

In light of this discussion, it is apparent that there is no federal requirements that a manufacturer recall a product or issue additional or amended warnings upon learning that a medical device potentially poses a health or safety risk. Thus, the claims in Counts I and II, which seek to impose liability for negligent failure to recall and negligent failure to warn based on information obtained post-FDA approval, would impose a

state requirement that is different from or in addition to the federal requirement.[4] Therefore, these claims are preempted by the MDA. Because the claims are preempted, Counts I and II fail to state claims for relief. Accordingly, the Court would not grant Plaintiffs leave to amend the complaint to assert the claims contained in Counts I and II.

Thus remaining for consideration is Count III, which states a claim for negligence per se for failure to comply with federal requirements consistent with state requirements. At first blush, this count appears to state nothing more than another variation of a fraud on the FDA claim. See Proposed Amended Complaint ¶ 54 ("Medtronic failed to comply with applicable CFR regulations in its Model 4004/400M PMA Supplement applications."). However, this count goes on to allege that the FDA's approval of the PMA Supplements established requirements for the design and manufacture of the leads and that Medtronic failed to manufacture the leads in accordance with the FDA requirements. Read in the light most favorable to Plaintiffs, this count fairly states a claim that Medtronic failed to build the leads in conformity with the approved PMA and PMA Supplements. This type of claim is not preempted by the MDA. See Kemp, 231 F.3d at 232. Therefore, with exception of striking ¶ 54, the Court would

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[4]The Court recognizes that Plaintiffs contend that Minnesota law imposes on manufacturers a continuing duty to warn of defects in products. The Court assumes without deciding that this duty includes a duty to recall defective products in certain circumstances. However, whether the law of a particular state recognizes the asserted cause of action is irrelevant to the analysis given that the liability Plaintiffs seek to impose would be a requirement different from or in addition to the federal requirement.

permit Plaintiffs to amend the complaint to state the claim alleged in Count III. Accordingly, to that extent, Plaintiffs' motion for leave to amend the Complaint is well-taken and is GRANTED.

The Court's rulings on the viability of the various claims has rendered much of the proposed amended complaint superfluous. Therefore, in order to simplify and clarify further proceedings, Plaintiffs shall within ten days of the date of this order file an amended complaint which conforms to the rulings of this order and contains only the factual allegations necessary to support the claim asserted in Count III of the proposed amended complaint.

Conclusion

In conclusion, the Court finds that Plaintiffs' motion to reopen the case is well-taken and is GRANTED. Plaintiffs' motion for leave to amend the complaint is GRANTED IN PART AND DENIED IN PART. Counts I, II, , IV, and V through VIII are preempted by federal law. Therefore, the motion for leave to amend the complaint to assert the claims in those counts is not well-taken and is DENIED. However, with the exception of ¶ 54, Count III of the proposed amended complaint is not preempted by federal law. Therefore, to that extent, the motion for leave to amend the complaint is well-taken and is GRANTED.

IT IS SO ORDERED

Date 12-10-01 /s/

Sandra S. Beckwith
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethel Cupek, et al.	)	
Plaintiffs,	)	Case No. C-1-97-105
	)	
vs.	)	
	)	
Medtronic, Inc.,	)	
Defendant.	)	

ORDER

This matter is before the Court on Plaintiffs' motion for reconsideration (Doc. No. 41). For the reasons set forth below, Plaintiffs' motion is not well-taken and is DENIED.

The Court described fully the procedural background of this case in its order of December 11, 2001 (Doc. No. 37). Suffice to say for present purposes that this case began with Plaintiffs suing Defendant Medtronic, Inc. under a number of state law tort and products liability theories because they were implanted with allegedly defective pacemaker leads manufactured by Medtronic. The case was then stayed while a case presenting identical legal issues, Kemp v. Medtronic,Inc., C-1-97-103, wound its way to a conclusion. Ultimately, in the Kemp case, this Court determined that except for claims that Medtronic failed to build a pacemaker lead in conformity with the applicable PMA and/or PMA Supplement, all state law tort claims and products liability claims were preempted by the Medical Device Amendments to the Food & Drug Act. 20 U.S.C. § 360(k)(a) [sic]. The Sixth Circuit Court of Appeals affirmed that decision. See Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000).

Following the Sixth Circuit's decision in Kemp, Medtronic moved to reopen this case for the purpose of filling a motion for summary judgment on Plaintiffs' claims. Plaintiff initially opposed reopening this case because a petition for a writ of certiorari was still pending before the U.S. Supreme Court in Kemp. Ultimately, however, the Supreme Court denied the petition and Plaintiffs conceded that it was time to reopen this case.

Upon reopening this case, however, Plaintiffs moved to file an amended complaint. See Doc. No. 32. Plaintiffs' proposed amended complaint would have retained each claim that was no longer legally viable in the wake of the Court's decision in Kemp and would have added new claims based on a theory that, after having learned that the 4004 and 4004M leads were dangerous, Medtronic was negligent in failing to recall these leads from the market and was negligent in failing to issue additional warnings on these leads. Medtronic opposed the motion for leave to amend on the grounds that Plaintiffs were either trying to redress claims that had already been rejected by the Sixth Circuit in Kemp and/or that their claims were futile because of MDA preemption.

On December 11, 2001, the Court issued an order granting in part and denying in part Plaintiffs' motion for leave to amend the complaint. Doc. No. 37. The court initially noted that Plaintiffs admitted that some to their claims were precluded by the Kemp decision, and therefore, would not permit Plaintiffs to re-allege those claims on the grounds of futility. The Court also found that Plaintiffs were attempting to reconfigure a fraud on the FDA claim—one of the claims rejected in Kemp and a claim which the U.S. Supreme Court subsequently held is preempted by the MDA—and, therefore, refused to allow Plaintiffs to amend their complaint to allege that claim. The Court also found that Plaintiff's claims related

to post-market failure to warn and failure to withdraw the leads from the market were preempted by the MDA. The Court, therefore, found that these claims were futile and declined to permit Plaintiffs to assert these claims in an amended complaint. The court did find, however, that the proposed amended complaint contained allegations that Medtronic failed to build the 4004 and 4004M leads in conformity with the requirements of the PMA and PMA Supplement. Therefore, the Court held that this claim was not futile and invited Plaintiffs to file an amend complaint containing only the factual allegations necessary to support such a claim.

Plaintiffs did not, however, file the amended complaint suggested by the Court. Instead, Plaintiffs filed the present motion for the Court to reconsider its order denying them leave to amend the complaint. Although the Court admits that it does not completely follow Plaintiffs' reasoning, they appear to argue that by addressing the perception issue at the amendment stage, the Court has both denied them of a full opportunity to brief the preemptive effect of MDA on the proposed claims and deprived them of the chance to save the preemption issue for appeal. The Court disagrees.

As the Court stated in the earlier order, when the opposing party argues that granting leave to amend would be futile, the district court's standard of review in assessing futility becomes the Rule 12(b)(6) standard of review. Rose v. Hartford Underwriters Ins. Co., 203 F.3d 417, 420 (6th Cir. 2000). In turn, the Rule 12(b)(6) standard assesses the legal sufficiency of the plaintiff's claims. See Miller v. Currie, 50 F.3d 373, 377 (6th Cir. 1995) (explaining that a court " should deny [a Rule 12(b)(6)] motion unless it is clear that the plaintiff can prove no set of facts in support of her claim that would entitle her to relief"); Mayer v. Mylod, 988 F.2d 635, 638 (6th Cir. 1993) ("The purpose of Rule 12(b)(6) is to allow a

defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even it everything alleged in the complaint is true."); Scheid v. Fanny Farmer Candy Shops, Inc., 859 F.2d 434, 436 (6th Cir. 1988) ('A Rule 12(b)(6) motion tests whether a cognizable claim has been pleaded in the complaint."). Therefore, in assessing whether to grant Plaintiffs leave to amend their complaint, the Court necessarily and correctly analyzed the preemptive effect of the MDA on Plaintiffs' proposed claims because preempted claims are not legally cognizable. It would turn the futility aspect of Rule 15(a) on its head to allow Plaintiffs to amend their complaint and then determine whether their claims are preempted.

Moreover, Plaintiffs had a fair opportunity to brief the preemptive effect of the MDA on their claims because Medtronic raised the issue in its memorandum in opposition to the motion for leave to amend and again in its notice of supplemental authority. See Doc. Nos. 34 & 36. Plaintiffs could have addressed preemption in their reply brief but instead focused on whether Minnesota law recognizes claim for post-market failure to warn. As the Court stated in the earlier order, whether Minnesota law permits such a claim is irrelevant if the liability Plaintiffs would impose is a requirement different than or in addition to the requirements of federal law. See Doc. No 37, at 18 n.2. The fact that Plaintiffs perhaps focused their attention in the wrong direction does not mean that they have been deprived of an opportunity to brief the merits of the preemption issue. Plaintiffs did not respond at all to Medtronic's notice of supplemental authority and so waived any further briefing opportunity there. In short, Plaintiffs had sufficient notice and opportunity to address preemption before the Court ruled on their motion for leave to amend.

Finally, the Court believes that the preemption issue has been preserved for appellate review. As stated, the futility

analysis incorporates the Rule 12(b)(6) standard. In denying Plaintiffs leave to amend their complaint on futility grounds, the Court has in effect dismissed those claims for failure to state claims upon which relief can be granted. The Court of Appeals will review that decision under the de novo standard of review rather than for abuse of discretion. See Blakely v. United States, 276 F.3d 853, 874 (6th Cir. 2002) ("[W]hen the district court's decision is based on the futility of the amendment, i.e., that the amended complaint would not withstand a motion to dismiss, we review the district court's decision de novo."). The Court of Appeals will not be able to make its decision without reviewing MDA preemption. Therefore, in the Court's opinion, Plaintiffs have not lost their right to appeal the Court's rulings on MDA preemption.

Accordingly, for the reasons state [sic], Plaintiff's motion for reconsideration is not well-taken and is DENIED.

IT IS SO ORDERED

Date 11-19-02 /s/
Sandra S. Beckwith
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethel Cupek, et al.	)	
Plaintiffs,	)	Case No. C-1-97-105
	)	
vs.	)	
	)	
Medtronic, Inc.,	)	
Defendant.	)	

ORDER

This matter is before the Court on Defendant Medtronic, Inc.'s motion for summary judgment (Doc. No. 29) and Plaintiffs' response to the Court's show cause order of September 14, 2003 (Doc. No. 65). For the reasons set forth below, Medtronic's motion for summary judgment is well-taken and is GRANTED.

The factual and procedural background of this case is well-documented in several other orders issued by the Court. See Doc. Nos. 37, 54, 62. The Court, therefore, need not again recount the case history. On September 14, 2003, the Court ordered Plainfiffs to show cause why Medtronic's motion for summary judgment should not be granted on their remaining state law claims for negligence per se in the manufacture of the 4004 and pacemaker leads.

In response, Plaintiffs state that in opposition to Medtronic's motion, they would present evidence that Medtronic deviated from the requirements of the PMA Supplement and the FDA conditions of approval by implementing changes to the thickness of the platinum

sputtering of pacemaker leads without submitting reports detailing the engineering changes to the FDA. See Doc. No. 65, at 6-10. Assuming, however, that Plaintiffs are in possession of such evidence and that it indeed shows that Medtronic changed the platinum sputtering thickness without submitting the required reports to the FDA, this evidence fails to establish that Medtronic was negligent per se in manufacturing Plaintiffs' pacemaker leads. This contention is only a slight tweaking of Plaintiffs' theory that the PMA supplements for the 4004 and 4004M leads required Medronic to manufacture the leads with a specific thickness of platinum sputtering. However, as this Court found in Kemp v. Medtronic, Inc., C-1-97-103 (S.D. Ohio 1999) (Doc. No. 210), and as affirmed by the Sixth Circuit Court of Appeals, Kemp v. Medronic, Inc., 231 F.3d 216, 232 (6th Cir. 2000), the FDA's approval of the leads only required Medtronic to make the leads with a platinum sputtering coating; it did not require Medtronic to apply a specific thickness of sputtering. Thus, even if Medtronic did vary the thickness of the platinum sputtering without filing the proper reports with the FDA, so long as the pacemakers leads had some platinum sputtering, and Plaintiffs do not contend that they did not, Medtronic was not negligent per se manufacturing the leads. To the extent that Plaintiffs contend that Medtronic was negligent per se in failing to file the proper reports with the FDA, that claim is preempted by federal law. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Therefore, summary judgment in Medtronic's favor on this theory of liability is appropriate.

Accordingly, for the reasons stated, Medtronic, Inc.'s motion for summary judgment is well-taken and is GRANTED. This case is closed.

IT IS SO ORDERED

Date January 13, 2004 /s/
Sandra S. Beckwith
United States District Judge

Supreme Court, U.S.
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NO. 05-22

IN THE
Supreme Court of the United States

M. R. KNISLEY, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

Respondent Medtronic, Inc. concedes the conflict among the lower federal and state courts on the question presented. It offers two arguments why the petition should nonetheless be denied. First, Medtronic contends that the courts on the no-preemption side of the conflict are going to reverse themselves. However, Medtronic made the same prediction in opposition to two petitions for certiorari filed four years ago, and time has proven the prediction to be wrong. Second, Medtronic argues that decisions finding no preemption are incorrect. Petitioners of course believe those decisions to be correct. Yet whichever group of cases has properly construed 21 U.S.C. § 360k(a) and *Medtronic v. Lohr*, 518 U.S. 470 (1996), the continuing conflict will not be resolved without the Court's intervention.

1. Medtronic does not deny that the lower courts are in conflict over the question presented in this case: whether the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval ("PMA"). Indeed, Medtronic does not dispute the existence of a conflict on either side of the preemption analysis: Medtronic (at 17) agrees that a conflict exists over whether premarket approval establishes a preemptive requirement on the federal side of the analysis. *Compare Goodlin v. Medtronic*, 167 F.3d 1367, 1373-77 (11th Cir. 1999) (PMA not a device-specific requirement for purposes of preemption under § 360k(a)), *and Weiland v. Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (PMA preempts damages claims), *and Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) (same). And Medtronic acknowledges (at 19) that the courts disagree over whether state-law damages claims, such as those at issue here, are too general to trigger

preemption under the Court's analysis in *Lohr* and the FDA's long-standing preemption regulation, 21 C.F.R. § 808.1. *Compare Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (failure-to-warn claim predicated upon general duties applicable to every manufacturer not preempted), *and Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (same), *with Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (state-law damages claims preempted by § 360k(a)), *and Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997) (same).

2. Unable to deny the conflict among the lower courts, Medtronic argues that the conflict may "diminish" in light of two implied preemption cases—*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000)—and an amicus brief in *Horn*, in which the United States reversed its position on the preemptive effect of PMA. Medtronic's speculation is unfounded.

First, Medtronic's focus on *Buckman* is a distraction, for that case does not address the question presented here. In fact, Medtronic made the same argument—that courts would revisit and reverse their no-preemption rulings in light of *Buckman*—in opposing the petitions for certiorari in *Kemp v. Medtronic*, No. 00-1766, and in *Martin v. Medtronic*, No. 01-441. Yet although four years have passed since *Buckman* was decided, the split in authority is as deep as ever.

That *Buckman* has not affected cases construing section 360k(a) is not surprising. In holding that a fraud-on-the-FDA claim is impliedly preempted, *Buckman* explicitly distinguished claims that "rely[] on traditional state tort law which had predated the federal [MDA] enactments in question." 531 U.S. at 353. Moreover, Buckman involved neither a PMA device

nor preemption under section 360k(a). *Buckman*'s only discussion of PMA appears in a description of the medical device regulatory scheme. *Id.* at 344. That description is taken wholly from FDA regulations and from *Lohr*, and thus has always been available to the courts on both sides of the post-*Lohr* conflict on which the petition is based. Aside from that background discussion, *Buckman* mentions PMA only in passing. *Id.* at 348, 349.

Likewise, Medtronic twice suggests (at 1, 15) without explanation that the Court's 2000 decision in *Geier* will affect the long-standing conflict on the question presented. *Geier* involved preemption under the National Highway Traffic Safety Act. The Court found no express preemption but held that the plaintiff's damages claims were impliedly preempted because they would frustrate the agency's objective with regard to a specific motor vehicle safety standard. *Geier* has had no effect on the development of case law involving preemption under section 360k(a), and Medtronic does not cite any case suggesting otherwise.

Last, Medtronic points to an amicus brief filed by the United States in *Horn*, 376 F.3d 163, a Third Circuit case in which the government argued that PMA preempts damages claims. That brief also will not spur the lower courts to alter their prior holdings. Generally, statements contained in amicus briefs do not have the requisite formality to warrant deference or other significant weight. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000). This principle is particularly important here, where the government twice filed amicus briefs in this Court arguing against preemption, but then disavowed its own arguments and filed an amicus brief in *Horn* taking the opposite position. *Compare* Br. of U.S. as Amicus Curiae in *Smith Industries*

Medical Systems v. Kernats, S. Ct. No. 96-1407, at 14-18 (filed Dec. 1997), *and* Br. of U.S. as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 15, 1996), *with* Br. of U.S. as Amicus Curiae in *Horn v. Thoratec, Corp.*, 3d Cir. No. 02-4597, 2004 WL 1443720 (filed May 14, 2004). Thus, in *Bates v. Dow Agrosciences*, where the United States filed an amicus brief arguing a position directly opposite to the position it took in an earlier brief, the Court gave the later brief little attention and no weight. *See generally* 125 S. Ct. 1788 (2005); *see also id.* at 1801 (rejecting argument that provision unambiguously preempts tort claims as "particularly dubious" given that the United States earlier advocated the contrary position).

Not only does the government's position in the *Horn* amicus brief contradict the arguments it made twice before this Court, it contradicts the FDA's previous construction of its own regulation, 21 C.F.R. § 808.1(d), to which *Lohr* gave substantial weight. *See* 518 U.S. at 496-97, 498-99; *id.* at 505-06 (Breyer, J., concurring). Thus, the amicus brief deserves no deference from the courts. *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see Mead Corp.*, 533 U.S. at 228 (degree of deference due to government depends on, among other things, consistency and formality of government's position); *cf. Maislin Indus. v. Primary Steel, Inc.*, 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning."). In these circumstances, far from diminishing the confusion, the *Horn* amicus brief adds to it.

Last Term in *Bates*, the Court rejected a pesticide manufacturer's sweeping preemption argument and the holdings

of a majority of the circuit courts, based on a preemption provision "similarly worded" to section 360k(a). 125 S. Ct. at 1800. *Bates* represents the latest in a series of cases in which the Court has disagreed with a majority of lower courts as to the effect of an express preemption provision on state-law damages claims. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 63-64 (2002); *Geier*, 529 U.S. at 867-68; *Lohr*, 518 U.S. at 492-502; *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). The lower courts' responses to the Court's recent preemption jurisprudence demonstrates, not that time will resolve the conflicts, but that the Court's guidance with respect to the specific question presented here is urgently needed.

3. Attempting to minimize the disarray in the lower courts, Medtronic focuses on a few of the cases cited in the petition and argues that the cases were wrongly decided and "unlikely to survive." Opp. 17. However, Medtronic does not cite a single case from any of the relevant federal circuits or state courts, or from the trial courts within those jurisdictions, that suggests that these appellate decisions will be revisited.

Medtronic's descriptions of the opinions it selects for discussion consistently mischaracterize the courts' analyses. First, Medtronic misrepresents the reasoning of *Goodlin v. Medtronic*, 167 F.3d 1367, omitting key aspects of the opinion and selectively quoting from two pages of a 10-page analysis. Opp. 17. Just as Medtronic does here, in *Goodlin*, Medtronic relied on the rigor of the PMA review. The Eleventh Circuit correctly understood, however, that the PMA process does not result in any regulation or substantive statement, but only in a finding that the company has demonstrated reasonable assurance of a device's safety and effectiveness. 167 F.3d at 1375. The court explained that "while a PMA review is considerably more rigorous and detailed than the premarket

review notification [510(k)] process at issue in [*Lohr v.*] *Medtronic*, it is, in fact, no more 'specific a requirement.'" *Id.* at 1376 (quoting *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997)).

Next, Medtronic sets its sights on *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, which also holds that PMA does not preempt damages claims. Citing 21 C.F.R. § 814.80, the generally applicable regulation prohibiting manufacturers from altering the manufacturing or labeling of a PMA device in ways inconsistent with the conditions of approval, Medtronic disputes *Weiland*'s statement that PMA imposes no substantive requirements on the design or manufacture of the device. Opp. 18. To begin with, the relevant FDA regulations regarding 510(k) devices are very similar to the PMA regulation cited as an example by Medtronic. *See* 21 C.F.R. § 807.81(a)(3) (prohibiting significant design or manufacturing changes prior to new 510(k) submission); *see also* 21 C.F.R. § 820.1 (good manufacturing practices regulations applicable to both PMA and 510(k) devices); *id.* § 801.109 (prescription device labeling regulations applicable to both PMA and 510(k) devices). Nonetheless, the Court in *Lohr* held that section 510(k) regulation did not trigger section 360k(a).

Furthermore, in the portion of *Weiland* cited by Medtronic, the court is simply explaining that the design of the device originated with the company, and that the FDA had the authority to impose specific design standards but had not done so. 721 N.E.2d at 1152-53. Although it is true that PMA imposes various requirements on a manufacturer, both *Lohr*, 518 U.S. at 500, and the relevant FDA regulation, 21 C.F.R. § 808.1, instruct courts to consider whether those requirements are device-specific and whether state-law damages claims are

counterparts to specific requirements. Notably, Medtronic never undertakes that analysis. That is, Medtronic never identifies just what requirement a state-law damages claim would impose on the company, much less how that requirement would be different from or in addition to a particular federal requirement imposed through the PMA process. *See also Bates*, 125 S. Ct. at 1799 ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.").

Turning to cases that hold that state-law damages claims are too general to fall within the preemptive scope of section 360k(a), Medtronic ignores many of the state-court decisions cited in the petition and focuses almost exclusively on *Oja v. Howmedica*, 111 F.3d 782. While conceding that *Oja* conflicts with the decision below, Medtronic faults *Oja* for "never directly consider[ing] whether a finding of liability under a state common law duty would 'have the effect of establishing a substantive requirement for a specific device.'" Opp. 20 (quoting *Oja*, 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500)). In fact, the Tenth Circuit did "directly consider" that possibility and expressly found that "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device.'" *Oja*, 111 F.3d at 789. Medtronic also criticizes *Oja* for purportedly failing to recognize that, in *Lohr*, five members of this Court would have held that state-law damages claims can, in some circumstances, impose requirements preempted by section 360k(a). But *Oja* is fully consistent with that approach. The opinion applies *Lohr* at every step, *see generally id.* at 788-89, and holds that the common-law claims at issue were based on generally applicable duties that did not relate specifically to devices.

In addition to *Oja* and other cases, the petition cites *Niehoff v. Surgidev*, 950 S.W.2d at 822, as a case holding that, under *Lohr*, state laws of general applicability that apply to all products fall outside the preemptive scope of section 360k(a). Medtronic (at 19 n.11) responds that *Niehoff* involved an investigational device, not a PMA device. That statement is correct, as the petition itself states, *see* Pet. 17 n.6, but irrelevant. *Niehoff*'s holding that generally applicable state-law claims are not preempted concerns the state-law side of the section 360k(a) preemption analysis and, therefore, applies with equal force to claims involving PMA devices. Medtronic's claim that *Niehoff* did not so hold is belied by the decision itself, *see* 950 S.W.2d at 822, and by a subsequent decision of the Kentucky Court of Appeals, which reads *Niehoff* precisely as Petitioners do. *See Leslie v. Cincinnati Sub-Zero Prods., Inc.*, 961 S.W.2d 799, 802-03 (Ky. App. 1998).

Similarly, *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004), addressed preemption under section 360k(a) and the FDA's preemption regulation, 21 C.F.R. § 808.1(d)(1), and held that the state law at issue was not preempted because it was a law of general applicability. Medtronic dismisses this case on the ground that it did not involve a PMA device or a damages claim. Again, the factual assertions are correct but irrelevant. The Iowa Supreme Court's reading of *Lohr* and the applicable FDA regulation conflicts with the decisions in damages cases involving PMA devices, such as *Mitchell*, 126 F.3d at 912, and *Horn*, 376 F.3d at 174-75, that hold that section 360k(a) can preempt state-law claims of general applicability.

4. In Petitioners' view, the decision below is inconsistent with the text and purpose of the MDA, with FDA regulations, and with this Court's decision in *Lohr*. Medtronic

disagrees. The petition and opposition reveal the parties' drastically different understandings of the law and the significance of the facts concerning the FDA approval of the 4004M pacemaker lead. For instance, Petitioners maintain that design specifications originate with the manufacturer and therefore are not specific federal requirements with preemptive force under section 360k(a), while Medtronic argues that PMA transforms the manufacturer's specifications into preemptive federal requirements. And although Medtronic cites various Federal Register notices and congressional reports, Petitioners believe that each supports their view when read in context.

If the Court grants the petition, there will be time enough to respond to Medtronic's merits arguments in detail. For present purposes, the depth of the disagreement on the merits only underscores the need for review. The parties' submissions make clear that courts have come down on both sides of the question presented, creating conflicts as to both aspects of the two-pronged analysis outlined in *Lohr*. In addition, as discussed in the petition (at 23-24), some courts have effectively ignored that analysis, disregarding, in particular, the Court's majority opinion with respect to the state-law side of the inquiry, which rejects preemption of generally applicable state law, such as the common-law duties on which Petitioners rely here. The conflicting decisions on the question presented, like the parties' positions, are irreconcilable and can be resolved only by this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts petitioners' state common law damages claims challenging the design, production, distribution, and labeling of Medtronic's Model 4004 and Model 4004M pacemaker leads, where those devices were granted pre-market approval (PMA) by the Food and Drug Administration (FDA) and where each of petitioners' claims would impose requirements relating to the safety or effectiveness of the devices that would be "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of those devices.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

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21 C.F.R. § 808.1(d)(1) 20, 25, 26

21 C.F.R. § 810.10 14

21 C.F.R. § 814.20 *et seq.* 6

21 C.F.R. § 814.39 24

21 C.F.R. § 814.80 ..... 18, 24

21 C.F.R. Pt. 820 8

21 C.F.R. § 820.01 *et seq.* 9

Final Rule, Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications, 43 Fed. Reg. 18,661 (May 2, 1978) 26

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MISCELLANEOUS

Amicus Curiae Brief, filed by the United States, in *Horn v. Thoratec Corp.*, 2004 WL 1143720 ..... *passim*

FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce, 97th Cong., 2d Sess. 5 (1982) 28

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BRIEF FOR THE RESPONDENT IN OPPOSITION

On at least two occasions in the last four years, this Court has denied petitions for certiorari virtually identical to the petition presented here. See *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001). The grounds for denying certiorari in those cases, already ample at that time, are even stronger today.

Contrary to petitioners' assertion (Pet. 1), the lower courts are *not* "deeply divided" regarding the application of *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Quite the opposite. A clear and growing consensus has emerged that—consistent with this Court's teaching in *Lohr*—FDA premarket approval (PMA) of a medical device preempts conflicting state law claims arising from the design, manufacture, distribution, and labeling of such a device. Every court of appeals to have considered the issue in the past five years has concluded, as did the Sixth Circuit below, that the FDA's vigorous PMA process establishes device-specific federal requirements that, pursuant to 21 U.S.C. § 360k(a), preempt state common law damages claims that would effectively create state requirements "different from" or "in addition to" the federal requirements.

While there is some vestigial inconsistency in the lower courts' interpretations of *Lohr*, the remaining conflict is increasingly stale and likely to disappear even without this Court's intervention. The only cases to hold that state common law damages claims are never preempted by PMA approval were decided nearly a decade ago, shortly after this Court's decision in *Lohr*. Since then, this Court's subsequent decisions in *Geier* v. *American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), have given clear guidance on the proper interpretation of *Lohr*. Moreover, just last year, the United States filed an *amicus curiae* brief in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), setting forth the FDA's considered opinion that, under the relevant FDA regu-

lation, approval of a medical device through the PMA process generally preempts state common law claims arising from the use of such a device. Given *Geier*, *Buckman*, and the recent *amicus* brief in *Horn*, the few lower courts that had initially misinterpreted *Lohr* are likely to revise their aberrant views without further action by this Court.

STATEMENT

The petition provides almost no information about either the claims that petitioners actually raised below or the lengthy and comprehensive PMA process to which the specific medical devices at issue were subjected. After briefly outlining the background legal structure applicable to preemption under the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, we set forth these critical facts.

A. The Regulatory Structure Of The Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the FDA to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA—in *Lohr* and, more recently, in *Buckman*. In a

fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state law tort actions challenging the design, manufacture, or labeling of "Class III" devices (*i.e.*, those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "premarket notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492-494.

Explicitly differentiating the 510(k) notification process, at issue in *Lohr*, from the PMA process at issue here, the *Lohr* Court noted that "[t]he § 510(k) notification process is by no means comparable to the PMA process." *Id.* at 478–479. Thus, "[b]efore a new Class III device may be introduced to the market" via the far more exacting PMA process,

> the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review. *Id.* at 479. Because the device at issue in *Lohr* had been marketed "without running the gauntlet of the PMA process," *id.* at 494, the *Lohr* Court never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one must engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that are arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504-505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506-507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process—which "is focused on *equivalence*, not safety" (*id.* at 493 (emphasis in original) (internal quotation omitted)) and which does "not 'require'" a medical device "to take any particular form for any particular reason" (*ibid.*)—did not preempt the state law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device and thus plaintiffs would not have been injured. The Court—noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (531 U.S. at 353)—found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the FDA claims would * * * cause applicants to fear that their disclosures to

the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 351.

B. The Extensive Regulatory History Of The Model 4004 And 4004M Devices.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 531 U.S. at 344; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. The path to approval of the Models 4004 and 4004M pacemaker leads at issue in this case demonstrates the thoroughness of that review.[1] When the FDA approved Medtronic's application for pre-market approval of the Model 4004M, on March 28, 1990, that approval was the culmination of a rigorous administrative process that began *eight years* earlier, with Medtronic's 1982 application for an investigational device exemption ("IDE") to permit clinical trials of a predecessor device, the Model 4003 lead. Before the FDA determined, in approving the Model 4004M and 4004 PMAs, that Medtronic had proffered valid scientific evidence providing a reasonable assurance that those leads were safe and effective for their intended use, the devices and their direct predecessor models (in particular, the Model 4003) had been rigorously reviewed and critically evaluated for safety and efficacy by the FDA, in light of the known and potential complications that could arise from their use, on numerous occasions between 1982 and 1990.

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[1] As explained further below (at 9–10), the Model 4004 was the immediate predecessor to the Model 4004M; the only difference between the two is a minor change to a connector pin. Both devices were subjected to similar agency review—the successor 4004M lead was approved through a "PMA supplement" to the 4004 lead approval. See page 10, *infra*; see also Pet. 11 n.3.

The following is a brief chronology of the FDA's review leading up to its approval of the Model 4004 and Model 4004M pacemaker leads.[2]

- Medtronic filed its initial IDE application for the Model 4003 lead on March 26, 1982.
- That application was denied by the FDA, in a letter dated May 6, 1982, pending submission of more detailed information regarding Medtronic's proposed clinical trial.
- Medtronic provided the requested information, and the FDA approved the IDE for the Model 4003 on June 28, 1982. The FDA prohibited any significant change in the investigation without advance FDA approval, however.
- Medtronic later requested authority to expand the clinical trial. In a June 29, 1983 letter, the FDA denied Medtronic's request and required it to continue the investigation under the existing limits.
- Medtronic filed its PMA application for the Model 4003 lead on September 30, 1983. The application contained all of the detailed product and labeling information required by 21 C.F.R. §§ 814.20 *et seq*.
- FDA staff reviewed the Model 4003 PMA application, and by letter of November 29, 1983, required Medtronic to submit additional information concerning (1) the animal and *in vitro* testing of the lead so that FDA reviewers could better evaluate the testing and (2) "the fate of the implanted lead, in terms of po-

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[2] This description is based on the affidavit of Charles H. Swanson, which is contained (at J.A. 98-119) in the Sixth Circuit's Joint Appendix in *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001), a case with which this case was consolidated for purposes of discovery. See Pet. App. 13a; see also *Kemp*, 231 F.3d at 219 (summarizing PMA history of Model 4004 and 4004M leads).

tential long term degradation of the insulating materials."

- Medtronic responded on February 14, 1984, providing detailed descriptions of completed testing as well as a compilation of published scientific literature and other relevant documents.
- On April 23, 1984, the FDA approved additional implants in the clinical trial, "for the purpose of determining whether or not to file a PMA," but required those implants to be performed by physicians who had particular experience recognizing potential complications from the leads.
- By letter of July 30, 1984, the FDA required Medtronic to supply additional information for its PMA review.
- Medtronic filed annual reports about the IDE trials of the 4003 lead yearly between 1983 and 1986.
- The FDA requested additional information about lead survival experience in the IDE investigation after receiving Medtronic's 1984 IDE annual report.
- In September 1985, Medtronic filed a supplement to the IDE, seeking FDA approval to permit fundamental design changes to be made in the lead and to revise the reporting requirements concerning field performance of the lead.
- Also in September 1985, Medtronic filed an amendment to its PMA application in response to the FDA's July 30, 1984 letter. Medtronic furnished extensive data regarding the performance of prior lead models through its chronic lead performance database and through information gleaned from returned product analyses.

- The FDA approved the supplemental IDE in October 1985.
- The FDA demanded additional test and clinical data regarding the Model 4003 as a part of the PMA review in December 1985, and required amendments to the proposed warranty language.
- Medtronic responded in March 1986 by filing another supplemental PMA that explained in greater detail technical aspects of the lead's design, compared those with prior lead models, and analyzed data on the performance of those prior lead models. In addition, Medtronic provided an analysis of data generated from the clinical trials of the 4003 lead.
- In April 1986—30 months after Medtronic first filed a PMA request—the FDA advised Medtronic that the Model 4003 PMA was "suitable for filing," and would undergo the scientific and compliance review provided for in 21 U.S.C. §§ 360c, 360e(c)(2). The FDA also advised Medtronic that it would have to demonstrate that its facilities complied with all applicable "Good Manufacturing Practice" (GMP) rules and regulations under 21 C.F.R. Pt. 820.
- On May 23, 1986, the FDA referred the Model 4003 application to a panel of independent scientists for review. The panel concluded that Medtronic had submitted "valid scientific evidence" sufficient to be used to evaluate the safety and effectiveness of the Model 4003 lead. The panel members concluded that the information provided reasonable assurance that the device was safe and effective for its intended use and that the reports of complications and adverse reactions did not outweigh the benefits from use of the device.

- Based upon the record before it, the FDA approved the PMA application for the Model 4003 lead on July 29, 1986.
- The FDA formally acknowledged the closure of the IDE investigation for the Model 4003 lead in April 1987.
- On July 15, 1988, Medtronic filed a PMA application for the Model 4004 lead, as a supplement to the PMA for the Model 4003. The new application again complied in full with the requirements of 21 C.F.R. § 820.01 *et seq.* in both content and detail. In addition to providing extensive information on the new product's configuration, *in vitro* and *in vivo* testing of electrical performance, biostability test data, clinical test data about a prototype model tested in Canada, and copies of all proposed labels and warranty documents, Medtronic provided details of a newly-developed biostability test that replicated in a laboratory setting an insulation failure mode experienced in prior lead models. Appendices contained extensive data on lead survivability, both from Medtronic's "Chronic Lead Study" and from the analysis of prior lead models returned from the field.
- In response to this application, the FDA required Medtronic to modify the labeling of the Model 4004 to state explicitly that clinical trials had been done only on a unipolar version of the lead. Medtronic complied by submitting a revised label to the agency.
- The FDA approved the Model 4004 PMA Supplement on February 10, 1989, judging that Medtronic had provided valid scientific evidence upon which it could conclude that the device was safe and effective for its intended use. The FDA required, as a condition of approval of the Model 4004 PMA, that a further PMA Supplement be filed before any change was

made to the device that could affect its safety or effectiveness. In addition, the FDA required Medtronic to continue to report, post-approval, on the performance of the lead.

- Medtronic filed another PMA Supplement, seeking approval for the sale of the Model 4004M lead, on October 31, 1989, primarily to obtain approval to use a new type of connector pin at the end of the lead.

- The FDA approved the PMA Supplement for the Model 4004M lead on March 28, 1990, subject to the same conditions of approval that governed the approval of the Model 4004 lead.

Thus, the regulatory review under the PMA process that led to the approval of the Model 4004 and 4004M leads lasted *eight years*—from March 1982 to March 1990—and entailed detailed exchanges between the FDA and Medtronic to ensure that the agency was fully satisfied as to the testing, safety, design, and labeling of the Model 4004M lead, the Model 4004 lead, and the predecessor models to these leads.

C. Petitioners' Cases In The Lower Courts.

1. Petitioners are individuals, or immediate relatives of individuals, who were implanted with pacemakers employing the Model 4004 and 4004M leads. Petitioners filed four separate lawsuits against Medtronic in the Southern District of Ohio, consolidated for all purposes on January 18, 2002, asserting that they were injured after the implanted leads purportedly malfunctioned.

In their initial complaints, the earliest version of which was filed on January 24, 1997, petitioners asserted 11 state common law causes of action, including claims for strict liability, negligence, negligence per se, negligent and fraudulent misrepresentation, failure to warn, breach of implied and

express warranties, and negligent and intentional infliction of emotional distress.[3]

2. Petitioners' cases were consolidated for purposes of discovery with *Kemp* v. *Medtronic, Inc.*, No. C-1-97-103 (S.D. Ohio), which presented basically identical factual assertions and legal claims.

The district court in *Kemp* granted summary judgment to Medtronic on all counts. See Pet. App. 9a-11a. In the first of two summary judgment decisions, the court held as a threshold matter that the PMA process establishes specific federal requirements that preempt common law claims that would have the effect of creating state requirements different from or in addition to those federal requirements. See *id.* at 10a. The court then found that the plaintiffs' design, warning, and warranty claims were preempted inasmuch as recovery would in fact impose state requirements different from or in addition to the federal requirements. See *ibid.* The court also granted summary judgment on plaintiffs' manufacturing defect claim on the basis of preemption, insofar as that claim alleged negligence despite adherence to the FDA-imposed requirements.[4] See *ibid.* The court did, however, grant plain-

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[3] The first suit to be filed was *Cupek* v. *Medtronic, Inc.*, No. C-1-97-105. *Padgett* v. *Medtronic, Inc.*, No. C-1-97-413, *Bocock* v. *Medtronic, Inc.*, No. C-1-98-148, and *Shindelman* v. *Medtronic, Inc.*, No. C-1-98-178, were filed subsequently. The complaints in *Cupek*, *Bocock*, and *Shindelman* were essentially identical; the *Padgett* complaint contained only a subset of the claims asserted in the other three cases. The cases were ultimately consolidated under *Cupek*. See docket entry 42 at J.A. 9, in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005). For ease of exposition, we will refer to the complaint in *Cupek*—which upon consolidation became the sole operative complaint—as petitioners' initial complaint. The case below was named for Ethel Cupek, the first named plaintiff in the first filed case, but she was voluntarily dismissed from the case in September 1998. See Pet. 14 n.4.

[4] The district court also granted Medtronic summary judgment on the plaintiffs' allegation of fraud on the FDA, holding that claim to be preempted as well. See Pet. App. 10a. See also *Kemp*, 231 F.3d at 216 & 233 n.14 (noting that plaintiffs' fraudulent misrepresentation claim—identical

tiffs leave to file an amended complaint alleging negligent deviation from the FDA-imposed manufacturing requirements, a claim that the court found would not be preempted. After a corresponding amended complaint was filed, the court issued a second summary judgment decision in favor of Medtronic, finding as a factual matter that Medtronic had not deviated from the federal requirements in manufacturing the 4004M lead. See *id.* at 11a.

The *Kemp* plaintiffs appealed to the Sixth Circuit. (The district court administratively closed these four consolidated cases while the Sixth Circuit considered the plaintiffs' appeal in *Kemp*. See Pet. App. 9a.) The Sixth Circuit affirmed the district court's judgment in all respects. See *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); Pet. App. 12a. Expressly agreeing with the Seventh Circuit, the court of appeals found that "'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'" 231 F.3d at 226–27 (quoting *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997)). The court of appeals further found that "a jury verdict in plaintiffs' favor * * * would amount to a state requirement 'different from, or in addition to,' the federal requirements." *Id.* at 232. Accordingly, the court held that plaintiffs' claims were "preempted by § 360k of the MDA." *Id.* at 237. The *Kemp* plaintiffs petitioned for certiorari, which this Court denied. See 534 U.S. 818 (2001).

3. Following the denial of certiorari in *Kemp*, petitioners in this case simultaneously moved to reinstate their case and for leave to file an amended complaint.

Petitioners' proposed amended complaint contained eight state law counts. Counts I and II alleged negligence and/or strict liability for failure to warn and failure to recall after

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to that asserted by petitioners here—was characterized by plaintiffs as, and necessarily based upon, an allegation of fraud on the FDA).

PMA approval had been received. Count III alleged negligence per se for failure to comply with federal requirements consistent with state requirements. Count IV alleged negligence per se for failure to comply with the conditions of approval. Counts V–VIII alleged strict liability, negligence, and breach of warranty in connection with the leads' design, manufacture and use. See Pet. App. 14a–15a.

The district court granted the unopposed motion to reinstate but denied petitioners leave to amend with respect to all counts but their proposed Count III. According to the court, the amendment was futile as to the remaining counts because those claims would all be preempted by federal law. See Pet. App. 18a–24a. The court instructed petitioners to file a new amended complaint limited only to their Count III (see *id.* at 23a–24a), but petitioners failed to do so (see *id.* at 27a).

Thereafter, the district court—relying on the Sixth Circuit's decision in *Kemp* and this Court's decision in *Buckman*—granted Medtronic summary judgment on petitioners' initial complaint. See Pet. App. 30a–31a.[5]

4. Petitioners appealed the district court's denial of leave to amend their complaint. See Pet. App. 4a.[6] The Sixth Circuit affirmed in all respects.

With respect to proposed Counts I and II, which alleged a failure to warn and a failure to recall after PMA approval had been received, the court of appeals noted that "the FDA requires continuous updates as part of the [PMA] process" and that "[t]hese updating requirements specifically address warnings and recalls associated with medical devices." Pet.

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[5] With respect to petitioners' claim of negligence per se, the district court found that, as a matter of fact, petitioners had failed to proffer any evidence to support the assertion that Medtronic had deviated from the FDA's manufacturing requirements. See Pet. App. 31a.

[6] Petitioners did not continue to press the assertions raised in their proposed Count III. See Pet. App. 4a.

App. 5a (citing 21 U.S.C. §§ 360h(a), 360(e)(1), 360h(e)(2)(a); 21 C.F.R. §§ 803.50, 810.10). Consequently, the court held, "[a]ny claim, under state law * * * that [Medtronic] failed to warn patients beyond warnings required by the FDA, or that [Medtronic] failed to recall a product without first going through the PMA supplement process would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process." *Id.* at 6a.[7] Accordingly, the court concluded, proposed Counts I and II were preempted under the MDA.

The court of appeals also affirmed the refusal to grant leave to amend as to proposed Count IV. The court explained that this claim was "a disguised fraud on the FDA claim" (*id.* at 5a) and that granting leave to amend would have been futile because this Court, in *Buckman*, had held that "federal law preempted such claims." *Ibid.*

Petitioners conceded that under *Kemp* their remaining proposed counts (Counts V–VIII), were preempted by federal law, but raised the denial of leave to amend as to these counts for purposes of issue preservation. See Pet. App. 7a, 15a; see also J.A. 120 in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005). The court of appeals—having already carefully analyzed and applied *Lohr* to identical claims in *Kemp* (see 231 F.3d at 223–25)—declined to revisit its prior decision, thus reaffirming its holding that state law claims for strict liability, negligence, and breach of warranty in connection with the design, manufacture, and marketing of a PMA-approved device are preempted by federal law. Pet. App. 7a.

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[7] The court of appeals also noted that petitioners' "proposed amended claims undermine [petitioners'] preemption arguments, because those claims assert that [Medtronic] has duties 'independent of any obligations . . . to comply with applicable federal regulations." Pet. App. 6a (omission in original); see also J.A. 114–15, in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005).

REASONS FOR DENYING THE PETITION

Petitioners assert (Pet. at 1–2, 15–20) that review is necessary in this case because of the purported disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. The Court should deny the petition, as it denied the virtually identical petitions filed in *Kemp* and *Martin*. As we explain in Part I.A, the lower courts are in significantly less disarray than petitioners suggest. Moreover, in light of the *amicus* brief recently filed by the United States in *Horn*—as well as this Court's decisions in *Buckman* and *Geier*—any lingering disagreement within the lower courts is now likely to disappear. See Part I.B, *infra*. In any event, given the extensive FDA scrutiny of the Model 4004 and Model 4004M pacemaker leads, the Sixth Circuit's decision is plainly correct. See Part II, *infra*.

I. THERE IS NO REASON FOR THIS COURT TO REVISIT ITS RULING IN *MEDTRONIC, INC.* V. *LOHR*.

A. Any Disagreements Among The Lower Courts Are Minimal And Diminishing.

Petitioners assert that the lower courts are "deeply divided" on the question whether the FDA's approval of a medical device through the PMA process preempts inconsistent state-law damages claims arising from the design, manufacture, and labeling of such devices. Pet. 15–16. Indeed, petitioners assert that there are conflicts as to both whether the PMA process imposes specific federal requirements and whether any duties imposed through state law damages actions can be preempted after *Lohr*. In fact, although a few courts, in outdated opinions, have misinterpreted *Lohr* on each of these issues, the great weight of authority—including *all* recent authority—favors the Sixth Circuit's position on each question.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to a device are preemptive under the MDA. See 518 U.S. at 500-501.[8] Based on this Court's discussion of the "rigorous" nature of the PMA process, and the Court's comparison between the 510(k) process (which "reflect[s] important but entirely generic concerns," *Lohr*, 518 U.S. at 501) and the PMA process (which focuses on "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements," *ibid.*), the vast majority of courts have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. See, *e.g.*, Pet. App. 5a; *McMullen* v. *Medtronic, Inc.*, No. 04-3678, 2005 WL 2043827 (7th Cir. Aug. 26, 2005); *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 171–73 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226-27; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v.

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[8] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's painstaking approval of the 4004M device through the PMA process easily satisfies that requirement. See pages 24–26, *infra*.

Allergan Med. Optics, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to the decisions of the Third, Fifth, Sixth, Seventh, and Eighth Circuits, as well as those of the Pennsylvania, Rhode Island, and Texas Supreme Courts, petitioners can identify (at Pet. 17) decisions of only one federal court of appeals and one state supreme court, *cf.* S. Ct. R. 10, that did not find PMA approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while at odds with the decision below, are internally confused and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found that the PMA process "is clearly specific to the device under review" and that the FDA's Conditions of Approval "constitute specific federal requirements," 167 F.3d at 1376, yet then somehow concluded that the requirements were not "applicable under [the MDA] to the device,'" *ibid.* (quoting 21 U.S.C. § 360k(a)(1)), and did not establish "a specific requirement that applies to a particular device," *id.* at 1377. The decision is not only internally inconsistent and factually incorrect, but also contrary to *Lohr*. The *Goodlin* court denied preemptive effect to the concededly specific federal requirements, apparently because the FDA's Conditions of Approval were "not promulgated with respect to [a] 'particular device.'" *Ibid.* Yet, so long as the specific federal requirement is applicable to a given device, *Lohr* does not demand that the requirement be applicable *exclusively* to that device. In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that no aspect of the PMA process is specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: First, the court

held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*)—a statement that is untrue both in general (see 21 C.F.R. § 814.80 (prohibiting the manufacturer from making any change without FDA authorization to a device that has been approved by the agency through the PMA process if such change would affect the device's safety or effectiveness)), and in this case, where the FDA repeatedly required modifications of the product and its labeling (see pages 5–10, *supra*). Second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, see 531 U.S. at 343, this decision is plainly incorrect.[9]

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[9] Petitioners' attempt to conflate the IDE process with the PMA process (see Pet. 17 n.6), in an effort to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite in footnote 6 are IDE rather than PMA cases and both specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996) (en banc); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), whereas the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination at the PMA stage that a product is safe and effective in light of all known risks should still preempt conflicting state requirements, including requirements imposed through common law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in question*, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

2. On the state side of the *Lohr* preemption equation, petitioners assert (at 18) that there is a "profound" split of authority over whether state law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts have held that such claims can be preempted,[10] a decision that is plainly correct under *Lohr* (see pages 26–28, *infra*). Only one federal court of appeals or state court of last resort, *cf.* S. Ct. R. 10, has relied on a contrary finding to limit the preemptive scope of the MDA—the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997).[11] *Oja* is one of the earliest appellate decisions to in-

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[10] See, *e.g.*, Pet. App. 6a; *McMullen*, 2005 WL 2043827, at *4; *Horn*, 376 F.3d at 173–177; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 213 F.3d at 224; *Mitchell*, 126 F.3d at 913-914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-118.

[11] Neither *Niehoff* nor *State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004), the only state supreme court decisions cited by petitioners, holds that state common law claims are not subject to preemption when a medical device has received FDA approval through the PMA process. Petitioners' parenthetical assertion that the Supreme Court of Kentucky, in *Niehoff*, held that state law damages claims are not specific requirements is based on a quotation taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common law damages claims. See 950 S.W.2d at 822 ("[t]he claim * * * of preemption to the defective design allegation fails because there is no specific federal requirement"). As discussed above (at page 18 n.10), the *Niehoff* court also focused on the significant differences between the PMA process and the IDE process. In *New Womyn*, a case brought by the state attorney general under the state's consumer fraud statute, the device at issue had not been approved by the FDA at all, let alone after "running the gauntlet of the PMA process." *Lohr*, 518 U.S. at 494. Indeed, an FDA "employee with extensive experience in the review of applications regarding new medical devices" testified that a device similar to that at issue in *New Womyn* "was on display in the public lobby of the FDA building in a collection of what the FDA labeled 'quack devices.'" *New Womyn*, 679 N.W.2d at 597. Thus, even if the Supreme Court of Iowa had discussed whether a state law damages claim could in theory be preempted (which it did not), there was no specific federal requirement in *New Womyn* to preempt any state law claim.

terpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.

For example, the Tenth Circuit never directly considered whether a finding of liability under a state common law duty would "have the effect of establishing a substantive requirement of a specific device"—even though the court earlier had acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More important, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common law damages actions impose "requirements" that can be preempted by federal requirements. See page 27, *infra*.[12]

This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In the eight years since *Oja*, there has been no movement by any other court toward that court's erroneous analysis. Moreover, given this Court's holding in *Bates* v. *Dow Agrosciences LLC*, 125 S. Ct. 1788, 1798 (2005), that the term "requirements" in the identically-worded FIFRA includes common law claims, the unanimous view of the other courts of appeals that such claims may be preempted, and the United States' similar view as expressed in its *amicus* brief in *Horn* (see pages 21–23, *infra*), there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*.

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[12] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to warn) arising from a device approved, at the time it was implanted, only through the 510(k) process (see 111 F.3d at 787 n.2), it held that the FDA's 510(k) review led to specific federal requirements—despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

B. The Lower Courts Should Be Allowed To Consider The Implications Of The FDA's *Amicus* Brief In *Horn*.

In *Lohr*, this Court recognized that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495–496. The Court further recognized that, as the federal agency to which Congress has delegated the authority to implement the MDA, the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted." *Id.* at 496 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Given "the ambiguity in the statute" and "the congressional grant of authority to the agency on the matter contained within it," the Court found it appropriate to "giv[e] substantial weight to the agency's view of the statute." *Ibid.*

The FDA has recently provided authoritative guidance on the scope of § 360k's preemptive effect in the PMA context. At the request of the Third Circuit, the United States submitted an *amicus* brief on behalf of the FDA in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (2004). The FDA's *amicus* brief explains at length and in detail why "FDA pre-market approval for a new medical device preempts state law tort judgments." Brief for United States as *Amicus Curiae*, 2004 WL 1143720, at *2.

With respect to the federal side of the equation, the FDA stated unequivocally that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device.'" *Id.* at *16. The FDA noted that "[a]lthough the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and

market the product in compliance with the specifications as approved by [the] FDA." *Id.* at *24.

With respect to the state side of the preemption equation, the FDA endorsed the view—subscribed to by a majority of the Justices in *Lohr*—that "state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action 'would impose a requirement different from, or in addition to, that applicable under the FDCA.'" *Id.* at *18 (quoting *Lohr*, 518 U.S. at 511 (O'Connor, J., concurring in part and dissenting in part)). The FDA observed that, absent an allegation that the device in question deviated from the requirements imposed by the FDA through the PMA process, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Ibid.*

The FDA also emphasized in its brief the "very strong public policy considerations" that support finding PMA approval preemptive of state common law claims. *Id.* at *25. According to the FDA—the agency charged with implementing the MDA—"[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices." *Ibid.* As the agency explained, during the PMA process it conducts "a thorough review of a substantial scientific record" (*id.* at *16) and performs a "careful balancing" of the benefits and risks associated with a particular device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law" (*id.* at *31).

Given the agency's "unique role in determining the scope of § 360k's pre-emptive effect" (*Lohr*, 518 U.S. at 495–496),

the FDA's clear guidance in *Horn* further demonstrates that there is no need for this Court to grant review in this case. The FDA's "reasoned analysis" (U.S. Br., 2004 WL 1143720, at *30) is entitled to substantial weight as "the agency's fair and considered judgment on the matter in question." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997) (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties). This is especially true when coupled with this Court's renewed recognition of "the PMA review's rigor" (*Buckman*, 531 U.S. at 348), and Justice Stevens' reminder that "in *Medtronic, Inc.* v. *Lohr*, [this Court] recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties" (*Geier*, 529 U.S. at 897 (Stevens, J., dissenting)).

There is simply no reason to believe that those few courts that misinterpreted *Lohr* soon after it was decided will not now take heed of the FDA's *amicus* brief in *Horn* and join the clear consensus finding state common law claims that would impose requirements that are "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of a device to be preempted by federal law. In the unlikely event that those courts, upon reconsideration, choose to adhere to their prior decisions, the Court can grant review at that time.

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT.

The decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, with the views of the FDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device

or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur, there must be a federal requirement, a state requirement, and some "differen[ce]" between the two. See 518 U.S. at 500. These criteria are easily satisfied here.

1. The Sixth Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific). Moreover, the decision below is entirely consistent with the views of the FDA, which has declared that the PMA process "establishes 'specific requirements' applicable to a 'particular device.'" *Amicus* Brief in *Horn*, 2004 WL 1143720, at *16.[13]

It is especially clear that in *this* case the PMA process established specific requirements applicable in particular to the Model 4004 and 4004M leads. We described above (at pages

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[13] The FDA's view is well supported by statute. Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See 21 U.S.C. §§ 331(e), 351(f)(1)(A)(i), 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360e(f), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

5–10) the arduous eight-year process that led to the FDA's decision to approve Medtronic's plans to distribute the 4004 and 4004M leads. During that process, "[t]he design of the lead, the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process." *Martin*, 254 F.3d at 584–85; see also *Kemp*, 231 F.3d at 226-27 ("'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'") (quoting *Mitchell*, 126 F.3d at 913).

Significantly, approval through the PMA process entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both safe and effective." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)); see also *Amicus* Brief in *Horn*, 2004 WL 1143720, at *16 ("The approval perforce embodies the agency's conclusion that there is a 'reasonable assurance of safety and effectiveness' of the device."). The determination that a product is safe and effective, made after weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" (21 U.S.C. § 360c(a)(2)(C))—in a process characterized by this Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 531 U.S. at 349)—is of necessity the determination that the attributes of that device are an appropriate compromise that should not be modified by state law. See *Amicus* Brief in *Horn*, 2004 WL 1143720, at *29 ("state co-regulation" through tort actions "may disrupt the careful balancing performed by [the] FDA in the PMA process").

The regulatory history confirms this point. Petitioners rely on 21 C.F.R. § 808.1(d), *cf.* Pet. 22, but—as evidenced by the FDA's *amicus* brief in *Horn*—that regulation is entirely consistent with holding that the PMA process establishes device-specific requirements. Section 808.1(d) explains that state or local requirements will be preempted

when the FDA "has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the [MDA]*." (emphasis added). The preamble to section 808.1(d) notes that a state cannot, through its own premarket approval process, establish requirements inconsistent with the FDA's premarket approval process, and further explains:

> For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully be marketed without application for premarket approval. * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Final Rule, Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) (emphasis added).

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the State. Congress specifically referred to this requirement as one that the FDA should allow to continue by expressly exempting it (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45-46. No such exemption would have been thought necessary if the PMA process did not establish requirements otherwise preemptive of the state law.

2. The Sixth Circuit also correctly found that petitioners' state law claims, to the extent those claims were based on a showing that the device should have been manufactured, designed or labeled in a manner different from that required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes pre-

empt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504-505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in part).[14] Where a state law tort action is based on a requirement that is not identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement. Indeed, as noted by the FDA, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Amicus* Brief in *Horn*, 2004 WL 1143720, at *18.

Here, the PMA process imposed specific requirements on Medtronic, including the requirement to make its Model 4004 and Model 4004M leads using the specific design approved, which encompassed using a particular material for the leads' insulation and using the manufacturing processes Medtronic described in its PMA application. The district court found that petitioners had proffered no evidence suggesting that Medtronic had deviated from the requirements imposed by the FDA through the PMA process. Pet. App. 31a. Thus, were a jury to impose liability on Medtronic under

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[14] Significantly, Justice Stevens, who wrote the plurality opinion in *Lohr*, has himself stated that *Lohr* "recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties." *Geier*, 529 U.S. at 897 (Stevens, J., dissenting). See also *Geier*, 529 U.S. at 867 (noting that "a majority of this Court" in *Lohr* recognized that state tort actions may be preempted as imposing conflicting "requirements"); *Bates*, 125 S. Ct. at 1798.

state law, that jury would of necessity be imposing a requirement "different from" or "in addition to" that imposed by the FDA under federal law.[15]

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review and nullification of the FDA's PMA decisions would run roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.

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In the final analysis, petitioners present this Court little evidence of a significant split in authority below; what inconsistencies there may be in the interpretation of *Lohr* are likely to be resolved in light of the FDA's *amicus* brief in *Horn* and through further litigation in the lower courts. Petitioners provide no good reason why the Court, having repeatedly de-

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[15] As the Sixth Circuit noted below, petitioners' proposed amended Counts I and II assert that under state law Medtronic "has duties 'independent of any obligations . . . to comply with applicable federal regulations.'" Pet. App. 6a. The court of appeals correctly observed that "[s]uch independent duties are, at the very least, 'in addition to' federal requirements, and may very well be 'different from' federal requirements." *Ibid.*

clined to review this issue, should grant review here, or why the issue deserves the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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